

=====
 Bp number: 02-022-60n  
 =====

App number: 2002-259XRAB      Begin movement: 2/20/02  
 Received: 1/22/02      End movement: 2/20/03  
 Institution: Monsanto      Begin release: 2/20/02  
 Recipient: Wheat      End release: 2/20/03  
 Status: Pending      Acre: 50.00  
 Effective date: 2/21/02      CBI status: CBI  
 Phenotype: HT - Glyphosate tolerant

Comments:

Resp person: [REDACTED]  
Parsed name: [REDACTED]Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield, MO 63198

Telephone: [REDACTED]      Fax: 636-737-7085

- |  | Initial  | Date         |
|--|----------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ apd ]  | [ 1/30/02 ]  |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist               | [ hwp ]* | [ 1/31/02 ]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex  | [ KLn ]  | [ 2/4/02 ]*  |
| 4. <input type="checkbox"/> State response                                     |          |              |

O/d	Loc	Site	Reg			
Interstate	*Dest*CO	*	*WR *	[ ]	[ ]	[ ]
Interstate	*Dest*KS	*	*SCR *	[ ]	[ ]	[ ]
Interstate	*Dest*MO	*	*SCR *	[ ]	[ ]	[ ]
Interstate	*Dest*MT	*	*WR *	[ ]	[ ]	[ ]
Interstate	*Dest*NE	*	*SCR *	[ ]	[ ]	[ ]
Interstate	*Dest*SD	*	*SCR *	[ ]	[ ]	[ ]
Interstate	*Dest*WY	*	*WR *	[ ]	[ ]	[ ]
Interstate	*Orig*CO	*	*WR *			
Interstate	*Orig*KS	*	*SCR *			
Interstate	*Orig*MO	*	*SCR *			
Interstate	*Orig*MT	*	*WR *			
Interstate	*Orig*NE	*	*SCR *			
Interstate	*Orig*SD	*	*SCR *			
Interstate	*Orig*WY	*	*WR *			
Release	*	*CO	* 1*WR *	[ ]	[ ]	[ ]
Release	*	*KS	* 1*SCR *	[ ]	[ ]	[ ]
Release	*	*NE	* 2*SCR *	[ ]	[ ]	[ ]
Release	*	*WY	* 1*WR *	[ ]	[ ]	[ ]

- |  |         |              |
|--|---------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ apd ] | [ 1/31/02 ]  |
| 6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw   | [ KLn ] | [ 2/21/02 ]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ KLn ] | [ 2/26/02 ]  |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |         |              |

MONSANTO



CONFIDENTIAL

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CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-259XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-022-601

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-259XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

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Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

February 20, 2002 - February 20, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Lines derived from Cultivar/Variety: Bobwhite

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**Monsanto Reference ID**

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**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [REDACTED]

(b) (4)  
(b) (4)

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [REDACTED]

(b) (4)

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

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**Monsanto Reference ID**

2002-259XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the term of the Notification. Ship up to 1000 pounds wheat seed to and from each location.

**ORIGIN:**

CO, KS, MO, MT, NE, SD, WY

**DESTINATION:**

CO, KS, MO, MT, NE, SD, WY

**Ship From:**

CO

\*[(b) (4)] Larimer County/Province, CO (b) (4) U.S.A

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO,  
(b) (4), (b) (6), (b) (7)(C)  
U.S.A

] - CBI

KS

\*[(b) (4)] (b) (4) Ellis  
County/Province, KS, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C)

] - CBI

\*[(b) (4)] Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

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**Monsanto Reference ID**  
2002-259XRAB

\*[ (b) (4)] USA (b) (4) Thomas County/Province, KS,

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

\*[ (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MT

\*[ (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

NE

\*[ (b) (4) Scotts Bluff County/Province,  
NE, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) NE, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**  
2002-259XRAB

\*[ (b) (4) ] Lincoln  
County/Province, NE, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
[ (b) (4), (b) (6), (b) (7)(C) ] NE, [ (b) (4), (b) (6), (b) (7)(C) ] U.S.A., [ (b) (4), (b) (6), (b) (7)(C) ]

] - CBI

**SD**

\*[ (b) (4) ] USA (b) (4) Brookings County/Province, SD,  
[ (b) (4) ] USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
[ (b) (4), (b) (6), (b) (7)(C) ] SD, [ (b) (4), (b) (6), (b) (7)(C) ] USA [ (b) (4), (b) (6), (b) (7)(C) ]

] - CBI

**WY**

\*[ (b) (4) ] Goshen County/Province, WY, (b) (4) U.S.A.  
[ (b) (4) ]

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
WY, [ (b) (4), (b) (6), (b) (7)(C) ] U.S.A, [ (b) (4), (b) (6), (b) (7)(C) ]

] - CBI

\*[ (b) (4) ] Albany County/Province, WY, (b) (4)  
U.S.A

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
WY, [ (b) (4), (b) (6), (b) (7)(C) ] U.S.A, [ (b) (4), (b) (6), (b) (7)(C) ]

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**  
2002-259XRAB

**Ship To:**

**CO**

\*[REDACTED] (b) (4) Larimer County/Province, CO, (b) (4) U.S.A

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO,  
[REDACTED] (b) (4), (b) (6), (b) (7)(C)  
U.S.A,

] - CBI

**KS**

\*[REDACTED] (b) (4) [REDACTED] Ellis  
County/Province, KS, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

\*[REDACTED] (b) (4) Sedgwick County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, [REDACTED] USA,  
[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

\*[REDACTED] (b) (4) Thomas County/Province, KS,  
(b) (4) USA

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Monsanto Reference ID  
2002-259XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO  
\*[ (b) (4) St. Louis County/Province, MO (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,  
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MT  
\*[ (b) (4) Gallatin County/Province, MT (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4) USA,  
(b) (4), (b) (6), (b) (7)(C)

] - CBI

NE  
\*[ (b) (4) Scotts Bluff County/Province,  
NE, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) NE, (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

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**Monsanto Reference ID**  
2002-259XRAB

\*[REDACTED] (b) (4) Lincoln  
County/Province, NE, (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) NE, [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

**SD**  
\*[(b) (4)] USA (b) (4) Brookings County/Province, SD,

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) SD [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

**WY**  
\*[(b) (4)] Goshen County/Province, WY (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
WY, [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

\*[(b) (4)] (b) (4) Albany County/Province, WY, (b) (4)  
U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
WY, [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

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**Monsanto Reference ID**

2002-259XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CO (1), KS (1), NE (2), WY (1)

**CO**

[REDACTED] (b) (4) Larimer County/Province, CO, U.S.A, 10  
acres. (979)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) CO (b) (4), (b) (6), (b) (7)(C)

] - CBI

**KS**

[REDACTED] (b) (4) Thomas County/Province, KS,  
USA, 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C)

] - CBI

**NE**

[REDACTED] (b) (4) Scotts Bluff County/Province,  
NE, U.S.A., 10 acres. (591)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) NE (b) (4), (b) (6), (b) (7)(C)

] - CBI

[REDACTED] (b) (4) Lincoln  
County/Province, NE, U.S.A., 10 acres (b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) NE (b) (4), (b) (6), (b) (7)(C)

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**Monsanto Reference ID**

2002-259XRAB

] - CBI

**WY**

[REDACTED] (b) (4) Goshen County/Province, WY, U.S.A., 10  
acres. [REDACTED] (b) (4)

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) WY, [REDACTED] U.S.A. [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



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MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
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PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

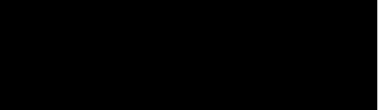
**Monsanto Reference ID**

2002-259XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C. Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C. Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).-

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costle, 622 F.2d 45, 51-52 (D.C. Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F. Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F. Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

#### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

#### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organsim appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO



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CHESTERFIELD, MISSOURI 63198  
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FAX (636) 737-7085  
<http://www.monsanto.com>

CBI-DELETED

**Monsanto Reference ID**

2002-259XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-022-60n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-259XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

February 20, 2002 - February 20, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Lines derived from Cultivar/Variety: Bobwhite

# CBI-DELETED

**Monsanto Reference ID**

2002-259XRAB

**designation of transformed line:** 33391**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

*CBI-DELETED*

**Monsanto Reference ID**

2002-259XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the term of the Notification. Ship up to 1000 pounds wheat seed to and from each location.

**ORIGIN:**

CO, KS, MO, MT, NE, SD, WY

**DESTINATION:**

CO, KS, MO, MT, NE, SD, WY

**Ship From:**

**CO**

[ CBI Deleted ] -- \*Larimer County/Province, CO, U.S.A

**KS**

[ CBI Deleted ] -- \*Ellis County/Province, KS

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

*CBI-DELETED*

**Monsanto Reference ID**  
2002-259XRAB

[ CBI Deleted ] -- \*Thomas County/Province, KS, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**NE**

[ CBI Deleted ] -- \*Scotts Bluff County/Province, NE, U.S.A.

*CBI-DELETED*

**Monsanto Reference ID**

2002-259XRAB

[ CBI Deleted ] -- \*Lincoln County/Province, NE, U.S.A.

**SD**

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA

**WY**

[ CBI Deleted ] -- \*Goshen County/Province, WY, U.S.A.

[ CBI Deleted ] -- \*Albany County/Province, WY, U.S.A

*CBI-DELETED*

**Monsanto Reference ID**  
2002-259XRAB

**Ship To:**

**CO**

[  CBI Deleted ] -- \*Larimer County/Province, CO, U.S.A

**KS**

[  CBI Deleted ] -- \*Ellis County/Province, KS

[  CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

[  CBI Deleted ] -- \*Thomas County/Province, KS, USA

*CBI-DELETED*

**Monsanto Reference ID**  
2002-259XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**NE**

[ CBI Deleted ] -- \*Scotts Bluff County/Province, NE, U.S.A.

*CBI-DELETED*

**Monsanto Reference ID**

2002-259XRAB

[ CBI Deleted ] -- \*Lincoln County/Province, NE, U.S.A.

**SD**

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA

**WY**

[ CBI Deleted ] -- \*Goshen County/Province, WY, U.S.A.

[ CBI Deleted ] -- \*Albany County/Province, WY, U.S.A

*CBI-DELETED*

**Monsanto Reference ID**

2002-259XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CO (1), KS (1), NE (2), WY (1)

**CO**

[  CBI Deleted ] -- Larimer County/Province, CO, U.S.A., 10 acres

**KS**

[  CBI Deleted ] -- Thomas County/Province, KS, USA, 10 acres

**NE**

[  CBI Deleted ] -- Scotts Bluff County/Province, NE, U.S.A., 10 acres

[  CBI Deleted ] -- Lincoln County/Province, NE, U.S.A., 10 acres

*CBI-DELETED*

**Monsanto Reference ID**  
2002-259XRAB

**WY**

[ CBI Deleted ] -- Goshen County/Province, WY, U.S.A., 10 acres

MONSANTO



CBI-DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

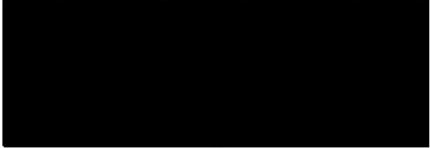
**Monsanto Reference ID**

2002-259XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-259XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-022-60n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-259XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)  
FAX 636/737-7085  
EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

February 20, 2002 - February 20, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Lines derived from Cultivar/Variety: Bobwhite

**Monsanto Reference ID**

2002-259XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Monsanto Reference ID**

2002-259XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

A total of 3000 pounds of seed may be shipped for the term of the Notification. Ship up to 1000 pounds wheat seed to and from each location.

**ORIGIN:**

CO, KS, MO, MT, NE, SD, WY

**DESTINATION:**

CO, KS, MO, MT, NE, SD, WY

**Ship From:**

**CO**

[ CBI Deleted ] -- \*Larimer County/Province, CO, U.S.A

**KS**

[ CBI Deleted ] -- \*Ellis County/Province, KS

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**Monsanto Reference ID**

2002-259XRAB

[ CBI Deleted ] -- \*Thomas County/Province, KS, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**NE**

[ CBI Deleted ] -- \*Scotts Bluff County/Province, NE, U.S.A.

**Monsanto Reference ID**

2002-259XRAB

[ CBI Deleted ] -- \*Lincoln County/Province, NE, U.S.A.

**SD**

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA

**WY**

[ CBI Deleted ] -- \*Goshen County/Province, WY, U.S.A.

[ CBI Deleted ] -- \*Albany County/Province, WY, U.S.A

**Monsanto Reference ID**

2002-259XRAB

**Ship To:**

**CO**

[  CBI Deleted ] -- \*Larimer County/Province, CO, U.S.A

**KS**

[  CBI Deleted ] -- \*Ellis County/Province, KS

[  CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

[  CBI Deleted ] -- \*Thomas County/Province, KS, USA

*11/19/2018*

**Monsanto Reference ID**  
2002-259XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**NE**

[ CBI Deleted ] -- \*Scotts Bluff County/Province, NE, U.S.A.

**Monsanto Reference ID**

2002-259XRAB

[ CBI Deleted ] -- \*Lincoln County/Province, NE, U.S.A.

**SD**

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA

**WY**

[ CBI Deleted ] -- \*Goshen County/Province, WY, U.S.A.

[ CBI Deleted ] -- \*Albany County/Province, WY, U.S.A

**Monsanto Reference ID**

2002-259XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CO (1), KS (1), NE (2), WY (1)

**CO**

[  CBI Deleted ] -- Larimer County/Province, CO, U.S.A., 10 acres

**KS**

[  CBI Deleted ] -- Thomas County/Province, KS, USA, 10 acres

**NE**

[  CBI Deleted ] -- Scotts Bluff County/Province, NE, U.S.A., 10 acres

[  CBI Deleted ] -- Lincoln County/Province, NE, U.S.A., 10 acres

**Monsanto Reference ID**

2002-259XRAB

**WY**

[ CBI Deleted ] -- Goshen County/Province, WY, U.S.A., 10 acres

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

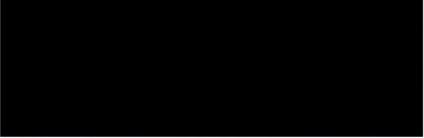
Monsanto Reference ID

2002-259XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

file copy

Mr. Mitch Yergert  
Colorado Department of Agriculture  
700 Kipling Street - Suite 4000  
Lakewood, CO 80215-5894

January 30, 2002

Dear Mr. Yergert:

Enclosed is notification 02-022-60n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-022-60n                      Applicant #: 2002-259XRAB  
Received: January 22, 2002                Effective: February 21, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: CO KS MO MT NE SD WY  
Release destination: CO KS NE WY

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009156



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

January 30, 2002

Dear Mr. Sim IV:

Enclosed is notification 02-022-60n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-022-60n                      Applicant #: 2002-259XRAB  
Received: January 22, 2002                      Effective: February 21, 2002  
Institution: Monsanto                              Recipient: Wheat  
Interstate destination: CO KS MO MT NE SD WY  
Release destination: CO KS NE WY

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_009157

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

January 30, 2002

Dear Mr. Brown:

Enclosed is notification 02-022-60n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-022-60n                      Applicant #: 2002-259XRAB  
Received: January 22, 2002                      Effective: February 21, 2002  
Institution: Monsanto                              Recipient: Wheat  
Interstate destination: CO KS MO MT NE SD WY  
Release destination: CO KS NE WY

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009158

file copy

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

January 30, 2002

Dear Mr. Ames:

Enclosed is notification 02-022-60n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-022-60n                      Applicant #: 2002-259XRAB  
Received: January 22, 2002                Effective: February 21, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: CO KS MO MT NE SD WY  
Release destination: CO KS NE WY

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[Signature]

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009159



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Stephen V. Johnson, State Entomologist  
Bureau of Plant Industry  
Nebraska Department of Agriculture  
301 Centennial Mall South - 4th Floor  
Lincoln, NE 68509-4756

January 30, 2002

Dear Mr. Johnson:

Enclosed is notification 02-022-60n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-022-60n                      Applicant #: 2002-259XRB  
Received: January 22, 2002                      Effective: February 21, 2002  
Institution: Monsanto                              Recipient: Wheat  
Interstate destination: CO KS MO MT NE SD WY  
Release destination: CO KS NE WY

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_009160

file copy

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

January 30, 2002

Dear Mr. Fridley:

Enclosed is notification 02-022-60n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-022-60n                      Applicant #: 2002-259XRAB  
Received: January 22, 2002                Effective: February 21, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: CO KS MO MT NE SD WY  
Release destination: CO KS NE WY

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009161

file copy

Mr. Henry R. Uhden, Agriculture Plant Industry Manager  
Consumer and Compliance Division  
Wyoming Department of Agriculture  
2219 Carey Avenue  
Cheyenne, WY 82002

January 30, 2002

Dear Mr. Uhden:

Enclosed is notification 02-022-60n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-022-60n                      Applicant #: 2002-259XRAB  
Received: January 22, 2002                Effective: February 21, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: CO KS MO MT NE SD WY  
Release destination: CO KS NE WY

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009162



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Mitch Yergert  
Colorado Department of Agriculture  
700 Kipling Street - Suite 4000  
Lakewood, CO 80215-5894

January 30, 2002

Dear Mr. Yergert:

Enclosed is notification 02-022-60n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-60n	Applicant #:	2002-259XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: CO KS MO MT NE SD WY			
Release destination: CO KS NE WY			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: MITCHELL YERGERT

Signature:

(b) (6), (b) (7)(C)

Date: FEB. 6, 2002

State: COLORADO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 6 2002

OR120018\_BR\_009163



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

January 30, 2002

Dear Mr. Brown:

Enclosed is notification 02-022-60n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-022-60n                      Applicant #: 2002-259XRAB  
Received: January 22, 2002                      Effective: February 21, 2002  
Institution: Monsanto                              Recipient: Wheat  
Interstate destination: CO KS MO MT NE SD WY  
Release destination: CO KS NE WY

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Michael E. Brown

Signature:

(b) (6), (b) (7)(C)

Date: 02/15/02

State: MO

Rptloc01/R4



APHIS • Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_009164

FEB 20 2002



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

January 30, 2002

Dear Mr. Ames:

Enclosed is notification 02-022-60n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-022-60n                      Applicant #: 2002-259XRB  
Received: January 22, 2002                      Effective: February 21, 2002  
Institution: Monsanto                              Recipient: Wheat  
Interstate destination: CO KS MO MT NE SD WY  
Release destination: CO KS NE WY

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 2/5/02

State: Montana

Rptloc01/R4



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FEB 5 2002

OR120018\_BR\_009165



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

January 30, 2002



Dear Mr. Fridley:

Enclosed is notification 02-022-60n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-60n	Applicant #:	2002-259XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: CO KS MO MT NE SD WY			
Release destination: CO KS NE WY			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

#### STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Kevin Fridley

Signature:

(b) (6), (b) (7)(C)

Date: 2/11/02

State: South Dakota

Rptloc01/R4



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OR120018\_BR\_009166

FEB 14 2002



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Henry R. Uhden, Agriculture Plant Industry Manager  
Consumer and Compliance Division  
Wyoming Department of Agriculture  
2219 Carey Avenue  
Cheyenne, WY 82002

January 30, 2002

Dear Mr. Uhden:

Enclosed is notification 02-022-60n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-022-60n	Applicant #:	2002-259XRAB
Received:	January 22, 2002	Effective:	February 21, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: CO KS MO MT NE SD WY			
Release destination: CO KS NE WY			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

(X) State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Jim Vibelow

Signature: (b) (6), (b) (7)(C)

Date: 2/5/02

State: WYOMING

Rptloc01/R4



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FEB 5 2002

TOTAL P.01

OR120018\_BR\_009167

February 21, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway N.  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2002.

**Interstate movement and Release**

Notification no. 02-022-60n (2002-259XRAB)

Regulated article - Wheat

Destinations - Colorado, Kansas, Missouri, Montana, Nebraska, South Dakota, Wyoming

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

CC:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
G. Ames, Montana Dept. of Agric., Helena, MT  
S. Johnson, Nebraska Dept. of Agric., Lincoln, NE  
K. Fridley, South Dakota Dept. of Agric., Pierre, SD  
H. Uhden, Wyoming Dept. of Agric., Cheyenne, WY  
File number 02-022-60n

# Confirmation Report-Memory Send

Time : Feb-25-02 06:24pm  
Tel line 1 :  
Tel line 2 :  
Name :

Job number : 488  
Date : Feb-25 06:22pm  
To : 916367377085  
Document Pages : 01  
Start time : Feb-25 06:23pm  
End time : Feb-25 06:24pm  
Pages sent : 01

Job number : 488

\*\*\* SEND SUCCESSFUL \*\*\*



Animal and  
Plant Health  
Inspection Service

Permits &  
Risk  
Assessments

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

February 21, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway N.  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 21, 2002.

Interstate movement and Release  
Notification no. 02-022-60n (2002-259XRAB)  
Regulated article - wheat  
Destinations - Colorado, Kansas, Missouri, Montana, Nebraska, South Dakota,  
Wyoming

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving state Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

CC:  
M. Yergert, Colorado Dept. of Agric., Lakewood, CO  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
G. Ames, Montana Dept. of Agric., Helena, MT  
S. Johnson, Nebraska Dept. of Agric., Lincoln, NE  
K. Fridley, South Dakota Dept. of Agric., Pierre, SD  
H. Uhden, Wyoming Dept. of Agric., Cheyenne, WY



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OR120018\_BR\_009169

*CONFIDENTIAL*

**2002 Wheat Field Test Report**

**USDA #02-022-60n**

**Monsanto #2002-259XRAB**

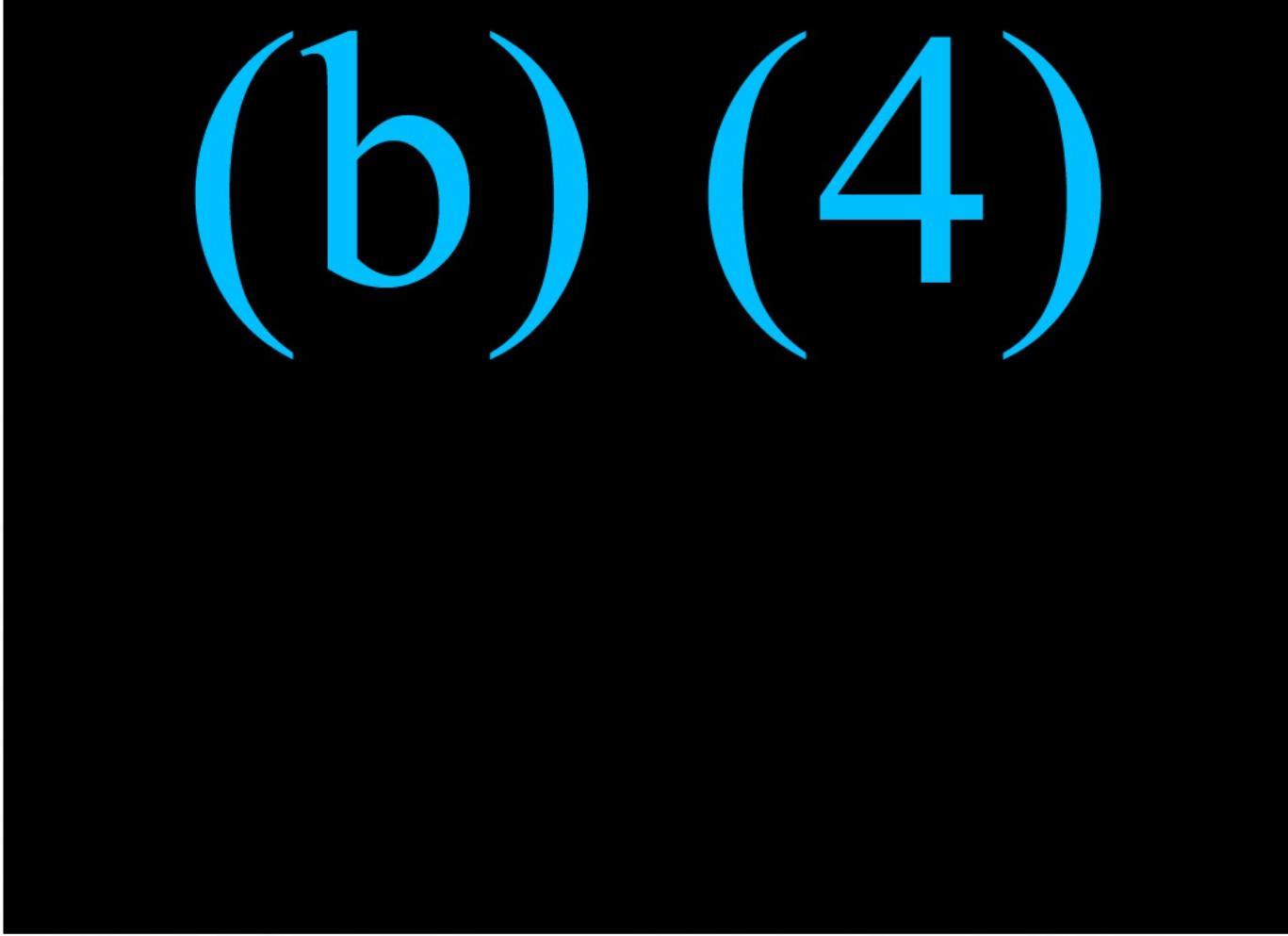
**August 8, 2003**

**Biotech Field Compliance Team  
Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
979	Larimer	CO
2147314659	Thomas	KS
2147303279	Lincoln	NE
591	Scotts Bluff	NE
2147303936	Goshen	WY

Larimer County/CO (979)

(b) (4)



(b) (4)

Thomas County/KS (2147314659)

(b) (4)

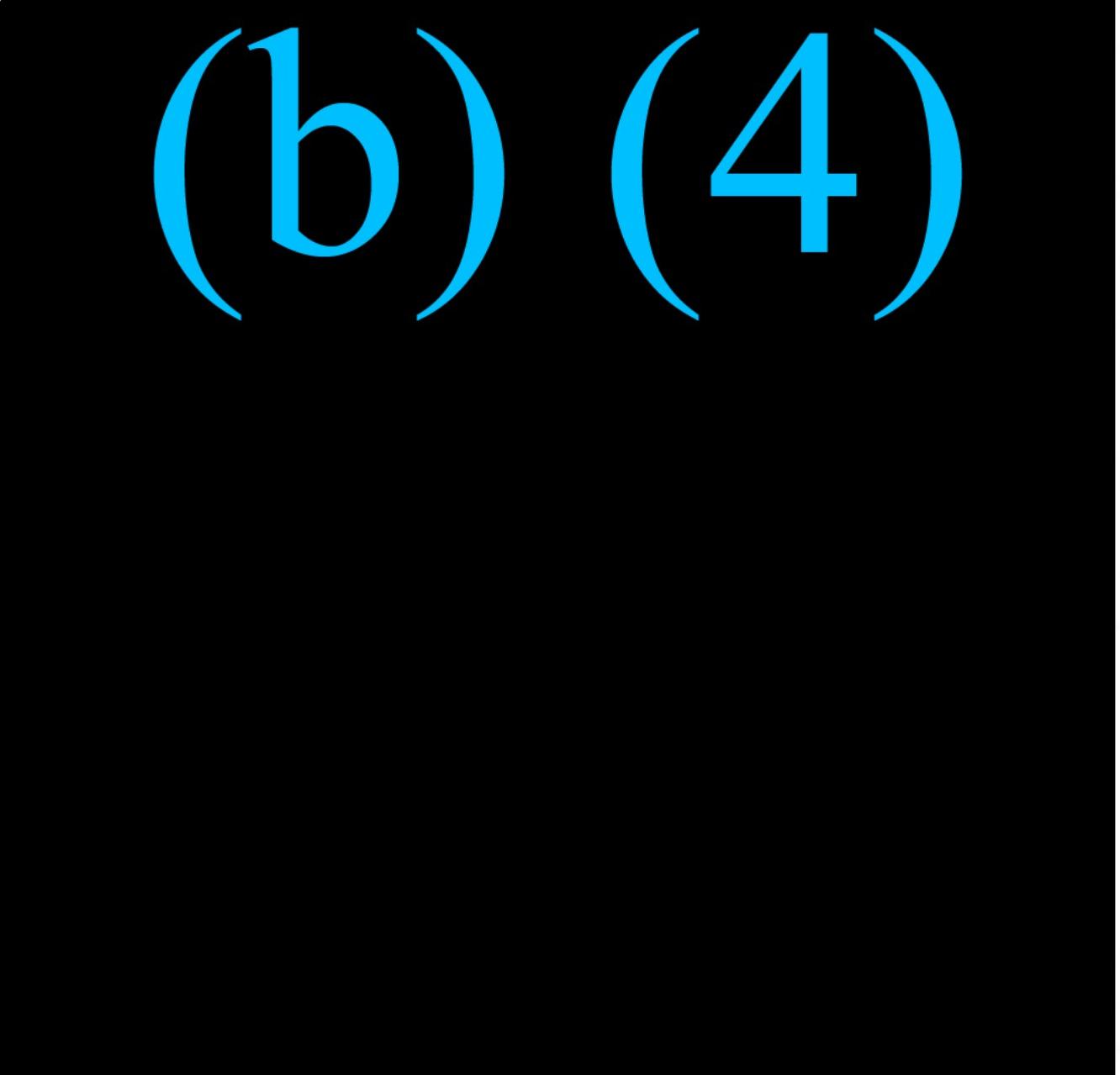
(b) (4)

Lincoln County/NE (2147303279)

(b) (4)

Scotts Bluff County/NE (591)

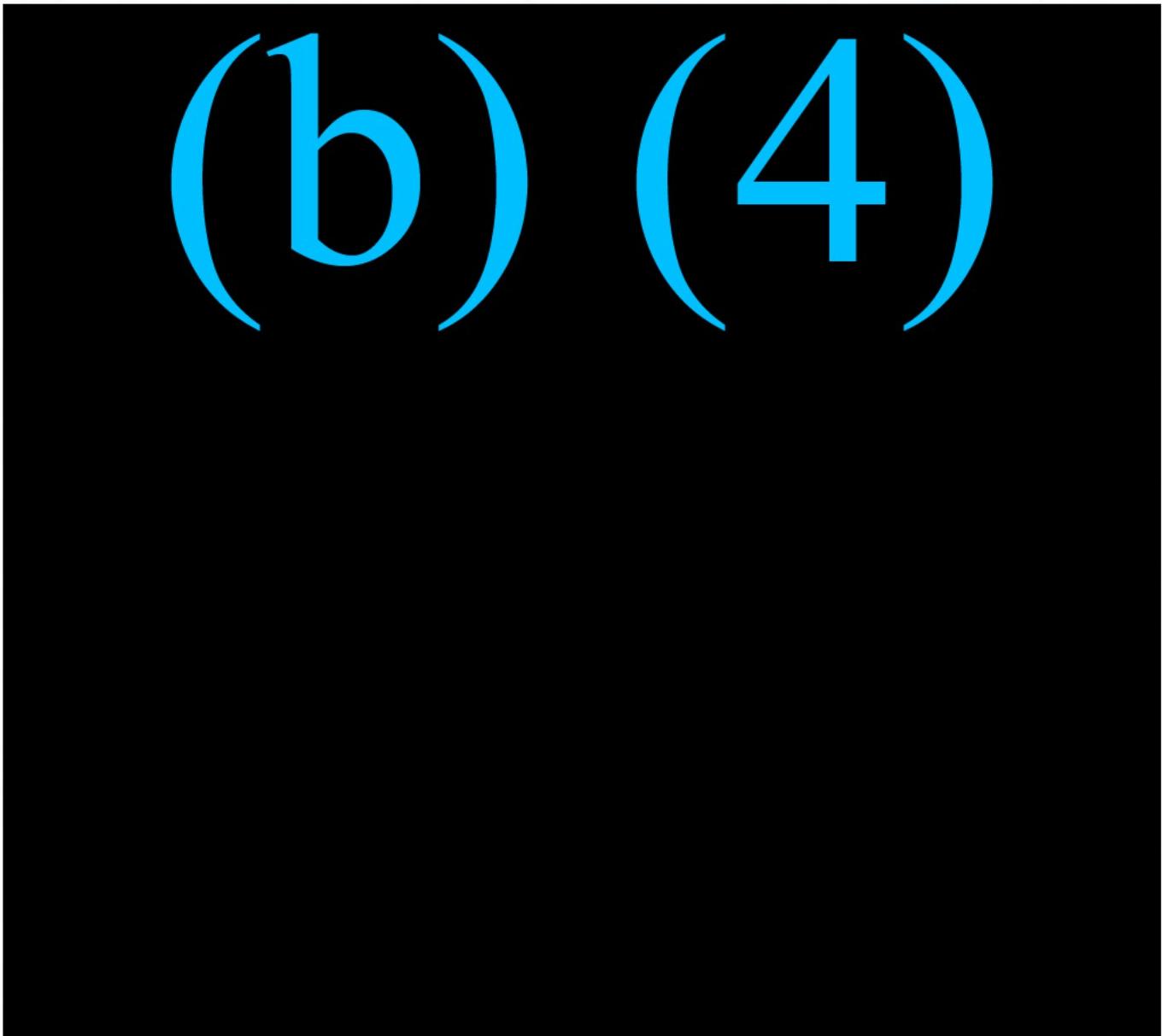
(b) (4)



Goshen County/WY (2147303936)

(b) (4)





## CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.<sup>1</sup>

<sup>1</sup> In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### **FIELD MONITORING DATA AS CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

*CBI-DELETED*

**2002 Wheat Field Test Report**  
**USDA #02-022-60n                    Monsanto #2002-259XRAB**

**August 8, 2003**

**Biotech Field Compliance Team  
Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
979	Larimer	CO
2147314659	Thomas	KS
2147303279	Lincoln	NE
591	Scotts Bluff	NE
2147303936	Goshen	WY

**Larimer County/CO (979)**

**Planting Date:** 04/12/2002

**Harvest Date:** 08/21/2002

**Destruct Date:** 08/23/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Thomas County/KS (2147314659)**

**Planting Date:** 03/29/2002

**Destruct Date:** 06/12/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

**Lincoln County/NE (2147303279)**

**Planting Date:** 04/01/2002

**Destruct Date:** 06/11/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

**Scotts Bluff County/NE (591)**

**Planting Date:** 04/01/2002

**Harvest Date:** 07/24/2002

**Destruct Date:** 08/30/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Goshen County/WY (2147303936)**

**Planting Date:** 04/04/2002

**Harvest Date:** 07/30/2002

**Destruct Date:** 09/06/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

2/04/02 10:43 am

## Notification Tracking Sheet

=====
 Bp number: 02-032-07n  
 =====

App number: 2001-811XRAB  
 Received: 2/01/02  
 Institution: Monsanto  
 Recipient: Wheat  
 Status: Pending  
 Effective date: 3/03/02  
 Phenotype: HT - Glyphosate tolerant  
 Begin movement: 2/20/02  
 End movement: 2/20/03  
 Begin release: 2/20/02  
 End release: 2/20/03  
 Acre: 20.00  
 CBI status: CBI

Comments:  
 Resp person:  
 Parsed name:

(b) (6), (b) (7)(C)

Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway N.  
 Address3:  
 Address4:  
 City/State/Zip: Chesterfield, MO 63198

Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

		Initial	Date
1.	[ <input checked="" type="checkbox"/> ] Assign Bp number and initial data entry	[ apd ]	[ 2/4/02 ]
2.	[ <input checked="" type="checkbox"/> ] Review by biotechnologist	[ DSH ] *	[ 2/5/02 ] *
3.	[ <input checked="" type="checkbox"/> ] Letter of notification to State Fed-ex	[ KLD ]	[ 2/16/02 ] *
4.	[ <input type="checkbox"/> ] State response		

O/d	Loc	Site	Reg				
Interstate	*Dest*KS	*	*SCR	*	[ ]	[ ]	
Interstate	*Dest*MO	*	*SCR	*	[ ]	[ ]	
Interstate	*Dest*MT	*	*WR	*	[ ]	[ ]	
Interstate	*Orig*KS	*	*SCR	*	[ ]	[ ]	
Interstate	*Orig*MO	*	*SCR	*	[ ]	[ ]	
Interstate	*Orig*MT	*	*WR	*	[ ]	[ ]	
Release	*	*MT	*	4*WR	*	[ ]	[ ]

5.	[ <input checked="" type="checkbox"/> ] Enter genes into database	[ apd ]	[ 2/5/02 ]
6.	[ <input checked="" type="checkbox"/> ] Letter of acknowledgement/denial/withdraw	[ KLD ]	[ 3/1/02 ] *
7.	[ <input checked="" type="checkbox"/> ] Enter final data into database	[ KLD ]	[ 3/5/02 ]
8.	[ <input type="checkbox"/> ] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

*CONFIDENTIAL*

**Monsanto Reference ID**

2001-811XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-032-07n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2001-811XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 636/737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

February 20, 2002 - February 20, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Lines derived from Cultivar/Hybrid: Bobwhite

**CONFIDENTIAL**

**Monsanto Reference ID**

2001-811XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**CONFIDENTIAL**

**Monsanto Reference ID**

2001-811XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

A total of 3000 pounds of seed may be shipped in the term of this Notification. Ship up to 1000 pounds wheat seed to and from each location.

**ORIGIN:**

KS, MO, MT

**DESTINATION:**

KS, MO, MT

**Ship From:**

KS

\*[(b) (4)] Sedgwick County/Province, KS [(b) (4)] USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] KS [(b) (4), (b) (6), (b) (7)(C)]  
USA

] - CBI

MO

\*[(b) (4)], St. Louis County/Province, MO [(b) (4)] USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] MO [(b) (4), (b) (6), (b) (7)(C)]  
USA

] - CBI

MT

\*[(b) (4)] Gallatin County/Province, MT [(b) (4)] USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] MT, [(b) (4), (b) (6), (b) (7)(C)] USA,

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**  
2001-811XRAB

\*[(b) (4), (b) (6), (b) (7)(C)] Pondera County/Province, MT, [(b) (4), (b) (6), (b) (7)(C)] USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] (b) (4), (b) (6), (b) (7)(C) MT, [(b) (4), (b) (6), (b) (7)(C)] USA,

] - CBI

\*[(b) (4)] Cascade County/Province, MT, [(b) (4)] USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] (b) (4), (b) (6), (b) (7)(C) MT, [(b) (4), (b) (6), (b) (7)(C)] USA,

] - CBI

\*[(b) (4), (b) (6), (b) (7)(C)] Judith Basin County/Province, MT, [(b) (4), (b) (6), (b) (7)(C)] USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] (b) (4), (b) (6), (b) (7)(C) Bozeman, MT, [(b) (4), (b) (6), (b) (7)(C)] USA,

] - CBI

\*[(b) (4)] (b) (4) Yellowstone County/Province, MT, [(b) (4)] USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] MT, [(b) (4), (b) (6), (b) (7)(C)] USA, [(b) (4), (b) (6), (b) (7)(C)]

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**  
2001-811XRAB

\*[REDACTED] (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) [REDACTED] MT, (b) (4) USA,  
(b) (4), (b) (6), (b) (7)(C)

] - CBI

**Ship To:**

**KS**

\*[REDACTED] (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) [REDACTED] KS, (b) (4), (b) (6), (b) (7)(C)  
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

**MO**

\*[REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) [REDACTED] MO, (b) (4), (b) (6), (b) (7)(C)  
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

**MT**

\*[REDACTED] (b) (4) Gallatin County/Province, MT, (b) (4) USA

**CONFIDENTIAL**

**Monsanto Reference ID**

2001-811XRAB

CONTACT: [REDACTED]  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

[REDACTED] MT, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

\*[REDACTED] (b) (4), (b) (6), (b) (7)(C) Pondera County/Province, MT, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: [REDACTED]  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MT, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

\*[REDACTED] (b) (4) Cascade County/Province, MT [REDACTED] (b) (4) USA

CONTACT: [REDACTED]  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MT, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

\*[(b) (4), (b) (6), (b) (7)(C)] Judith Basin County/Province, MT, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: [REDACTED]  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

[REDACTED] MT, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

*CONFIDENTIAL*

**Monsanto Reference ID**  
2001-811XRAB

\*[REDACTED] (b) (4) [REDACTED] Yellowstone County/Province,  
MT, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
[REDACTED] MT, [REDACTED] USA [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

\*[REDACTED] (b) (4) [REDACTED] Gallatin County/Province, MT, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] MT, [REDACTED] USA,  
(b) (4), (b) (6), (b) (7)(C)

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2001-811XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT (4)

MT

(b) (4)

Gallatin County/Province, MT, USA, 5 acres.

(b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C)

Pondera County/Province, MT, USA, 5 acres.

(b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C)

Judith Basin County/Province, MT, USA, 5 acres.

(b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

MT, USA, 5 acres. (b) (4)

(b) (4)

Yellowstone County/Province,

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



*CONFIDENTIAL*

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

Monsanto Reference ID

2001-811XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C. Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C. Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982)..

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costle, 622 F.2d 45, 51-52 (D.C. Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F. Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F. Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

#### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organsim appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



GB1-DELETED

**Monsanto Reference ID**

2001-811XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-032-07n

**1. USDA Reference Number**

2. Applicant Reference Number 2001-811XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 636/737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

February 20, 2002 - February 20, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article****Phenotypic Category:**

HT

**Phenotype:**

Glyphosate tolerant

Lines derived from Cultivar/Hybrid: Bobwhite

*CBI-DELETED*

**Monsanto Reference ID**

2001-811XRAB

**designation of transformed line:** 33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

*CBI-DELETED*

**Monsanto Reference ID**

2001-811XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

A total of 3000 pounds of seed may be shipped in the term of this Notification. Ship up to 1000 pounds wheat seed to and from each location.

**ORIGIN:**

KS, MO, MT

**DESTINATION:**

KS, MO, MT

**Ship From:**

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

*CBI-DELETED*

**Monsanto Reference ID**  
2001-811XRAB

[ CBI Deleted ] -- \*Pondera County/Province, MT, USA

[ CBI Deleted ] -- \*Cascade County/Province, MT, USA

[ CBI Deleted ] -- \*Judith Basin County/Province, MT, USA

[ CBI Deleted ] -- \*Yellowstone County/Province, MT, USA

*CBI-DELETED*

**Monsanto Reference ID**

2001-811XRAB

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**Ship To:**

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

*CBI-DELETED*

**Monsanto Reference ID**  
2001-811XRAB

[ CBI Deleted ] -- \*Pondera County/Province, MT, USA

[ CBI Deleted ] -- \*Cascade County/Province, MT, USA

[ CBI Deleted ] -- \*Judith Basin County/Province, MT, USA

*CBI-DELETED*

**Monsanto Reference ID**

2001-811XRAB

[ CBI Deleted ] -- \*Yellowstone County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

*CBI-DELETED*

**Monsanto Reference ID**

2001-811XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT (4)

**MT**

[ CBI Deleted ] -- Gallatin County/Province, MT, USA, 5 acres

[ CBI Deleted ] -- Pondera County/Province, MT, USA, 5 acres

[ CBI Deleted ] -- Judith Basin County/Province, MT, USA, 5 acres

[ CBI Deleted ] -- Yellowstone County/Province, MT, USA, 5 acres

MONSANTO



CB1-DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

Monsanto Reference ID

2001-811XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63108  
<http://www.monsanto.com>

*(REDACTED)*

**Monsanto Reference ID**

2001-811XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-032-07n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2001-811XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)  
FAX 636/737-7085  
EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis MO 63198

**4. Duration of Introduction**

Interstate Movement and Release February 20, 2002 - February 20, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Lines derived from Cultivar/Hybrid: Bobwhite

**Monsanto Reference ID**

2001-811XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Monsanto Reference ID**

2001-811XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

A total of 3000 pounds of seed may be shipped in the term of this Notification. Ship up to 1000 pounds wheat seed to and from each location.

**ORIGIN:**

KS, MO, MT

**DESTINATION:**

KS, MO, MT

**Ship From:**

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**Monsanto Reference ID**  
2001-811XRAB

[ CBI Deleted ] -- \*Pondera County/Province, MT, USA

[ CBI Deleted ] -- \*Cascade County/Province, MT, USA

[ CBI Deleted ] -- \*Judith Basin County/Province, MT, USA

[ CBI Deleted ] -- \*Yellowstone County/Province, MT, USA

**Monsanto Reference ID**  
2001-811XRAB

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**Ship To:**

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**Monsanto Reference ID**  
2001-811XRAB

[ CBI Deleted ] -- \*Pondera County/Province, MT, USA

[ CBI Deleted ] -- \*Cascade County/Province, MT, USA

[ CBI Deleted ] -- \*Judith Basin County/Province, MT, USA

**Monsanto Reference ID**

2001-811XRAB

[ CBI Deleted ] -- \*Yellowstone County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**Monsanto Reference ID**

2001-811XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT (4)

**MT**

[  CBI Deleted ] -- Gallatin County/Province, MT, USA, 5 acres

[  CBI Deleted ] -- Pondera County/Province, MT, USA, 5 acres

[  CBI Deleted ] -- Judith Basin County/Province, MT, USA, 5 acres

[  CBI Deleted ] -- Yellowstone County/Province, MT, USA, 5 acres

MONSANTO



(251-10441771)

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63108  
<http://www.monsanto.com>

Monsanto Reference ID

2001-811XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

February 4, 2002

Dear Mr. Sim IV:

Enclosed is notification 02-032-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-032-07n                      Applicant #: 2001-811XRAB  
Received: February 1, 2002                      Effective: March 3, 2002  
Institution: Monsanto                              Recipient: Wheat  
Interstate destination: KS MO MT  
Release destination: MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_009211

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 4, 2002

Dear Mr. Brown:

Enclosed is notification 02-032-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-032-07n                      Applicant #: 2001-811XRAB  
Received: February 1, 2002                      Effective: March 3, 2002  
Institution: Monsanto                              Recipient: Wheat  
Interstate destination: KS MO MT  
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Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[S]

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009212

file copy

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

February 4, 2002

Dear Mr. Ames:

Enclosed is notification 02-032-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-032-07n	Applicant #:	2001-811XRAB
Received:	February 1, 2002	Effective:	March 3, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[S]

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009213



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 4, 2002

Dear Mr. Brown:

Enclosed is notification 02-032-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-032-07n                      Applicant #: 2001-811XRAB  
Received: February 1, 2002                      Effective: March 3, 2002  
Institution: Monsanto                              Recipient: Wheat  
Interstate destination: KS MO MT  
Release destination: MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

Y State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 02/15/02

State: MO

Rptloc01/R4



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5010 20 2002

OR120018\_BR\_009214



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

February 4, 2002

Dear Mr. Ames:

Enclosed is notification 02-032-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-032-07n                      Applicant #: 2001-811XRAE  
Received: February 1, 2002                      Effective: March 3, 2002  
Institution: Monsanto                              Recipient: Wheat  
Interstate destination: KS MO MT  
Release destination: MT

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori W. Ham

Signature: (b) (6), (b) (7)(C)

Date: 2/7/02

State: Montana

Rptloc01/R4



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FEB 7 2002

OR120018\_BR\_009215

March 1, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C),

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 3, 2002.

Interstate movement and Release  
Notification no. 02-032-07n (2001-811XRAB)  
Regulated article - Wheat  
Destinations - Kansas, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

CC:

T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept of Agric., Jefferson City, MO  
G. Ames, Montana Dept. of Agric., Helena, MT  
File number 02-032-07n

# Confirmation Report-Memory Send

Time : Mar-01-02 06:39pm  
Tel line 1 :  
Tel line 2 :  
Name :

Job number : 656  
Date : Mar-01 06:38pm  
To : 916367377085  
Document Pages : 01  
Start time : Mar-01 06:38pm  
End time : Mar-01 06:39pm  
Pages sent : 01

Job number : 656      \*\*\* SEND SUCCESSFUL \*\*\*



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Permits &  
Risk  
Assessments

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

March 1, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to  
7 CFR 340.3(c), effective on or after March 3, 2002.

Interstate movement and Release  
Notification no. 02-032-07n (2001-811XRAB)  
Regulated article - Wheat  
Destinations - Kansas, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

cc:  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
G. Ames, Montana Dept. of Agric., Helena, MT



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_009217

*CONFIDENTIAL*

**2001 Wheat Field Test Report**  
**USDA #02-032-07n**      **Monsanto #2001-811XRAB**

**September 4, 2003**

**Biotech Field Compliance Team**  
**Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
2147307561	Gallatin	MT
2147314639	Pondera	MT
2147314638	Judith Basin	MT
7697	Yellowstone	MT

Gallatin County/MT (2147307561)

(b) (4)

(b) (4)

Pondera County/MT (2147314639)

(b) (4)

(b) (4)

Judith Basin County/MT (2147314638)

(b) (4)

(b) (4)

Yellowstone County/MT (7697)

(b) (4)

(b) (4)

## CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.<sup>1</sup>

---

<sup>1</sup> In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

## FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

*CBI-DELETED*

**2001 Wheat Field Test Report**  
**USDA #02-032-07n**      **Monsanto #2001-811XRAB**

**September 4, 2003**

**Biotech Field Compliance Team**  
**Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
2147307561	Gallatin	MT
2147314639	Pondera	MT
2147314638	Judith Basin	MT
7697	Yellowstone	MT

**Gallatin County/MT (2147307561)**

**Planting Date:** 04/23/2002

**Harvest Date:** 09/12/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Monitoring for Volunteer Plants:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

**Pondera County/MT (2147314639)**

**Planting Date:** 05/01/2002

**Harvest Date:** 09/13/2002

**Destruct Date:** 09/13/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

**Judith Basin County/MT (2147314638)**

**Planting Date:** 04/30/2002

**Harvest Date:** 09/13/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Monitoring for Volunteer Plants:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

**Yellowstone County/MT (7697)**

**Planting Date:** 04/09/2002

**Harvest Date:** 08/07/2002

**Destruct Date:** 08/09/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

=====
 Bp number: 02-046-17n  
 =====

App number: 2002-379XRAB      Begin movement: 3/13/02  
 Received: 2/15/02      End movement: 3/13/03  
 Institution: Monsanto      Begin release: 3/13/02  
 Recipient: Wheat      End release: 3/13/03  
 Status: Pending      Acre: 12.00  
 Effective date: 3/17/02      CBI status: CBI  
 Phenotype: HT - Glyphosate tolerant

Comments:

Resp person:

Parsed name:

Address1: Monsanto Company

Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield MO 63198

Telephone: (b) (6), (b) (7)(C)

Fax:

636-737-7085

=====

- |  | Initial   | Date          |
|--|-----------|---------------|
| 1. [✓] Assign Bp number and initial data entry | [ apd ]   | [ 2/21/02 ]   |
| 2. [✓] Review by biotechnologist               | [ DSH ] * | [ 2/21/02 ] * |
| 3. [ ] Letter of notification to State Fed-ex  | [ KLN ]   | [ 2/21/02 ] * |
| 4. [ ] State response                          |           |               |

O/d	Loc	Site	Reg			
Interstate	*Dest*MN	*	*NER	*	[ ]	[ ]
Interstate	*Dest*MO	*	*SCR	*	[ ]	[ ]
Interstate	*Orig*MN	*	*NER	*	[ ]	[ ]
Interstate	*Orig*MO	*	*SCR	*	[ ]	[ ]
Release	*	*MN	*	4*NER	*	[ ]
5. [✓]	Enter genes into database				[ apd ]	[ 2/21/02 ]
6. [✓]	Letter of acknowledgement/denial/withdraw				[ KLN ]	[ 3/26/02 ] *
7. [✓]	Enter final data into database				[ KLN ]	[ 3/29/02 ]
8. [ ]	If deny, reason:	Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify				



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

*CONFIDENTIAL*

**Monsanto Reference ID**

2002-379XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-046-17n

**1. USDA Reference Number****2. Applicant Reference Number** 2002-379XRAB**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 13, 2002 - March 13, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article****Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite and elite lines

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-379XRAB

designation of transformed line:

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [REDACTED]

(b) (4)  
(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [REDACTED]

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-379XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens  
**8. Introduction** Interstate Movement and Release  
2000 pounds seeds

**ORIGIN:** **DESTINATION:**  
MN, MO MN, MO

**Ship From:**

MN

\*[ (b) (4) ] Polk County/Province,  
MN, (b) (4) USA

CONTACT: [ (b) (4), (b) (6), (b) (7)(C) ] (b) (4), (b) (6), (b) (7)(C)  
[ (b) (4), (b) (6), (b) (7)(C) ] MN, [ (b) (4), (b) (6), (b) (7)(C) ] USA [ (b) (4), (b) (6), (b) (7)(C) ]

] - CBI

\*[ (b) (4) ] Ramsey County/Province, MN,  
(b) (4) U.S.A.

CONTACT: [ (b) (4), (b) (6), (b) (7)(C) ] (b) (4), (b) (6), (b) (7)(C)  
[ (b) (4), (b) (6), (b) (7)(C) ] MN, [ (b) (4), (b) (6), (b) (7)(C) ] U.S.A. [ (b) (4), (b) (6), (b) (7)(C) ]

] - CBI

\*[ (b) (4) ] Dakota  
County/Province, MN [ (b) (4) ] U.S.A.

CONTACT: [ (b) (4), (b) (6), (b) (7)(C) ] (b) (4), (b) (6), (b) (7)(C)  
[ (b) (4), (b) (6), (b) (7)(C) ] MN [ (b) (4), (b) (6), (b) (7)(C) ] U.S.A. [ (b) (4), (b) (6), (b) (7)(C) ]

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**  
2002-379XRAB

\*[ (b) (4) ] Stevens County/Province, MN,  
**(b) (4)** USA

CONTACT: [ (b) (4), (b) (6), (b) (7)(C) ]  
MN [ (b) (4), (b) (6), (b) (7)(C) ] USA

] - CBI

**MO**

\*[ (b) (4) ] St. Louis County/Province, MO, [ (b) (4) ] USA

CONTACT: [ (b) (4), (b) (6), (b) (7)(C) ] MO, [ (b) (4), (b) (6), (b) (7)(C) ]  
USA, [ (b) (4), (b) (6), (b) (7)(C) ]

] - CBI

**Ship To:**

**MN**  
\*[ (b) (4) ] Polk County/Province,  
MN [ (b) (4) ] USA

CONTACT: [ (b) (4), (b) (6), (b) (7)(C) ]  
[ (b) (4), (b) (6), (b) (7)(C) ] MN, [ (b) (4), (b) (6), (b) (7)(C) ] USA

] - CBI

\*[ (b) (4) ] Ramsey County/Province, MN,  
**(b) (4)** U.S.A.

CONTACT: [ (b) (4), (b) (6), (b) (7)(C) ]  
MN [ (b) (4), (b) (6), (b) (7)(C) ] U.S.A.

] - CBI

# CONFIDENTIAL

Monsanto Reference ID  
2002-379XRAB

\* [REDACTED] (b) (4) [REDACTED] Ramsey County/Province, MN,  
**(b) (4)** U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
MN [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
U.S.A.

] - CBI

\* [REDACTED] (b) (4) [REDACTED] Stevens County/Province, MN,  
**(b) (4)** USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
MN [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
USA

] - CBI

MO

\* [REDACTED] (b) (4) [REDACTED] St. Louis County/Province, MO **(b) (4)** USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] MO, [REDACTED]  
USA **(b) (4), (b) (6), (b) (7)(C)**

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-379XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MN (4)

**MN**

USA, 3 acres. (b) (4) [REDACTED] Polk County/Province, MN,

**RESPONSIBLE PERSON/RESEARCHER:** (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

U.S.A., 3 acres. (b) (4) [REDACTED] Ramsey County/Province, MN,

**RESPONSIBLE PERSON/RESEARCHER:** (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

[REDACTED] (b) (4) [REDACTED] Dakota  
County/Province, MN, U.S.A., 3 acres. (b) (4) [REDACTED]

**RESPONSIBLE PERSON/RESEARCHER:** (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

3 acres. (b) (4) [REDACTED] Stevens County/Province, MN, USA,

**RESPONSIBLE PERSON/RESEARCHER:** (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA,

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-379XRAB

] - CBI

MONSANTO



*CONFIDENTIAL*

**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

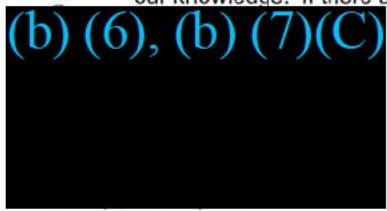
Monsanto Reference ID

2002-379XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C. Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C. Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982)..

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costle, 622 F.2d 45, 51-52 (D.C. Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



CBI-DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-379XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-046-17n

**1. USDA Reference Number**

2. Applicant Reference Number 2002-379XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 13, 2002 - March 13, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article****Phenotypic Category:**

HT

**Phenotype:**

Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite and elite lines

# CBI-DELETED

**Monsanto Reference ID**

2002-379XRAB

**designation of transformed line:** 33391**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

*CBI-DELETED*

**Monsanto Reference ID**

2002-379XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

2000 pounds seeds

**ORIGIN:**

MN, MO

**DESTINATION:**

MN, MO

**Ship From:**

**MN**

[ CBI Deleted ] -- \*Polk County/Province, MN, USA

[ CBI Deleted ] -- \*Ramsey County/Province, MN, U.S.A.

[ CBI Deleted ] -- \*Dakota County/Province, MN, U.S.A.

**CBI-DELETED**

**Monsanto Reference ID**

2002-379XRAB

[ CBI Deleted ] -- \*Stevens County/Province, MN, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Ship To:**

**MN**

[ CBI Deleted ] -- \*Polk County/Province, MN, USA

[ CBI Deleted ] -- \*Ramsey County/Province, MN, U.S.A.

*CBI-DELETED*

**Monsanto Reference ID**

2002-379XRAB

[ CBI Deleted ] -- \*Ramsey County/Province, MN, U.S.A.

[ CBI Deleted ] -- \*Stevens County/Province, MN, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-379XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MN (4)

**MN**

[ CBI Deleted ] -- Polk County/Province, MN, USA, 3 acres

[ CBI Deleted ] -- Ramsey County/Province, MN, U.S.A., 3 acres

[ CBI Deleted ] -- Dakota County/Province, MN, U.S.A., 3 acres

[ CBI Deleted ] -- Stevens County/Province, MN, USA, 3 acres

MONSANTO



CBI-DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Monsanto Reference ID

2002-379XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Monsanto Reference ID  
2002-379XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 27037

02-046-17n

1. USDA Reference Number
2. Applicant Reference Number 2002-379XRAB
3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)  
FAX 636/737-7085  
EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis MO 63198

4. Duration of Introduction

Interstate Movement and Release March 13, 2002 - March 13, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite and elite lines

**Monsanto Reference ID**

2002-379XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Monsanto Reference ID**

2002-379XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens  
**8. Introduction** Interstate Movement and Release  
2000 pounds seeds

**ORIGIN:**

MN, MO

**DESTINATION:**

MN, MO

**Ship From:**

**MN**

[ CBI Deleted ] -- \*Polk County/Province, MN, USA

[ CBI Deleted ] -- \*Ramsey County/Province, MN, U.S.A.

[ CBI Deleted ] -- \*Dakota County/Province, MN, U.S.A.

**Monsanto Reference ID**

2002-379XRAB

[  CBI Deleted ] -- \*Stevens County/Province, MN, USA

**MO**

[  CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Ship To:**

**MN**

[  CBI Deleted ] -- \*Polk County/Province, MN, USA

[  CBI Deleted ] -- \*Ramsey County/Province, MN, U.S.A.

**Monsanto Reference ID**  
2002-379XRAB

[ CBI Deleted ] -- \*Ramsey County/Province, MN, U.S.A.

[ CBI Deleted ] -- \*Stevens County/Province, MN, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Monsanto Reference ID**

2002-379XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MN (4)

**MN**

[  CBI Deleted ] -- Polk County/Province, MN, USA, 3 acres

[  CBI Deleted ] -- Ramsey County/Province, MN, U.S.A., 3 acres

[  CBI Deleted ] -- Dakota County/Province, MN, U.S.A., 3 acres

[  CBI Deleted ] -- Stevens County/Province, MN, USA, 3 acres

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

GENETICALLY ENGINEERED

**Monsanto Reference ID**

2002-379XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

[Redacted area]  
Monsanto Company

file copy

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

February 20, 2002

Dear Dr. Hanks:

Enclosed is notification 02-046-17n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-046-17n	Applicant #:	2002-379XRAB
Received:	February 15, 2002	Effective:	March 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[Signature]

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009254

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 20, 2002

Dear Mr. Brown:

Enclosed is notification 02-046-17n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-17n                      Applicant #: 2002-379XRAB  
Received: February 15, 2002                Effective: March 17, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: MN MO  
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(S)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009255



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

*faxed 3-25-02*

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

February 20, 2002

Dear Dr. Hanks:

Enclosed is notification 02-046-17n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-17n      Applicant #: 2002-379XRB  
Received: February 15, 2002      Effective: March 17, 2002  
Institution: Monsanto      Recipient: Wheat  
Interstate destination: MN MO  
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination, with the attached additional conditions.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 3-25-02

State: MN

Rptloc01/R4





## Minnesota Department of Agriculture

(651) 296-1277

March 25, 2002

Ms. Mary Jackson  
Biotechnology Program Operations  
Permit Unit  
USDA APHIS  
4700 River Road  
Riverdale, MD 27037

RE: Additional Conditions for Release of Wheat 02-046-17n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain entering commercial grain markets must be at least 100 feet.
3. Because of the possibility of volunteers:
  - Wheat should not be grown within the field trial area nor within 10 feet of the field trial area during the subsequent growing season and any wheat volunteers appearing within this area should be destroyed prior to flowering.
  - If wheat grown for harvest as grain is grown within 330 feet of the field trial during the year of the field trial, then wheat intended for use as seed should not be grown within this area during the following year.

These conditions are in addition to those contained in the applicants "Wheat Field Release Performance Standards" as revised January 2002.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

Sincerely,

**(b) (6), (b) (7)(C)**

Mary J. Hanks, Ph.D.  
State Biotechnologist



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 20, 2002

Dear Mr. Brown:

Enclosed is notification 02-046-17n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-17n                      Applicant #: 2002-379XRAB  
Received: February 15, 2002                Effective: March 17, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: MN MO  
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

*Michael E. Brown*

Signature: \_\_\_\_\_

(b) (6), (b) (7)(C)

Date: 02/26/02

State: MO

Rptloc01/R4



APHIS • Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_009258

FEB 28 2002

March 26, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C):

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 26, 2002.

Interstate movement and Release  
Notification no. 02-046-17n (2002-379XRAB)  
Regulated article - Wheat  
Destinations - Minnesota, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Minnesota concurs with APHIS determination with (attached) additional conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

CC:

M. Hanks, Minnesota Dept. of Agric., St. Paul, MN  
M. Brown, Missouri Dept of Agric., Jefferson City, MO  
File number 02-046-17n

OR120018\_BR\_009259



## Minnesota Department of Agriculture

(651) 296-1277

March 25, 2002

Ms. Mary Jackson  
Biotechnology Program Operations  
Permit Unit  
USDA APHIS  
4700 River Road  
Riverdale, MD 27037

RE: Additional Conditions for Release of Wheat 02-046-17n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain entering commercial grain markets must be at least 100 feet.
3. Because of the possibility of volunteers:
  - Wheat should not be grown within the field trial area nor within 10 feet of the field trial area during the subsequent growing season and any wheat volunteers appearing within this area should be destroyed prior to flowering.
  - If wheat grown for harvest as grain is grown within 330 feet of the field trial during the year of the field trial, then wheat intended for use as seed should not be grown within this area during the following year.

These conditions are in addition to those contained in the applicants "Wheat Field Release Performance Standards" as revised January 2002.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

Sincerely,

(b) (6), (b) (7)(C)

Mary L Hanks, Ph.D.  
State Biotechnologist



## Minnesota Department of Agriculture

(651) 296-1277

April 12, 2002

Ms. Mary Jackson  
Biotechnology Program Operations  
Permit Unit  
USDA APHIS  
4700 River Road  
Riverdale, MD 27037

Fax: 301-734-8910

RE: Further Amendments to Minnesota's Conditions for the Release of Herbicide Tolerant Wheat

Mary,

Following this note, you will find three letters that make further modifications to Minnesota's conditions for the release of herbicide tolerant wheat. I apologize for any confusion or extra work this might cause you or the applicants.

After discussion with the applicants and several of the project cooperators, Minnesota has decided to modify the State's planting restrictions in areas adjacent to the trial area during the year subsequent to the planting of the regulated material. Minnesota will no longer restrict the planting of wheat the year after the trial in the area beyond the 100 ft. isolation or buffer area. Conditions are specified clearly in the letters.

Thank you for your patience and assistance in getting this amendment to the applicant.

Sincerely  
**(b) (6), (b) (7)(C)**

Mary J. Hanks, Ph.D.  
State Biotechnologist



## Minnesota Department of Agriculture

(651) 296-1277

April 12, 2002

Ms. Mary Jackson  
Biotechnology Program Operations  
Permit Unit  
USDA APHIS  
4700 River Road  
Riverdale, MD 27037

**RE: AMENDMENT - Additional Conditions for Release of Wheat 02-046-17n**

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain entering commercial grain markets must be at least 100 feet.
3. Because of the possibility of volunteers:
  - Wheat should not be grown within the field trial area nor within the 100 ft isolation area around the field trial area during the subsequent season and any wheat volunteers appearing within this area should be destroyed prior to flowering.

These conditions are in addition to those contained in the applicant's "Wheat Field Release Performance Standards" as revised January 2002.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

(b) (6), (b) (7)(C)

Mary J. Franks, Ph.D.  
State Biotechnologist

*CONFIDENTIAL*

**2002 Wheat Field Test Report**  
**USDA #02-046-17n**      **Monsanto #2002-379XRAB**

**September 19, 2003**

**Biotech Field Compliance Team**  
**Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
2147303429	Polk	MN
424036936	Ramsey	MN
8025	Dakota	MN
2147308819	Stevens	MN
		Not Planted

Polk County/MN (2147303429)



(b) (4)

A large black rectangular redaction box covers the majority of the page below the Polk County entry. Inside this box, the letters "(b) (4)" are printed in a large, light blue font.

Ramsey County/MN (424036936)



(b) (4)

A large black rectangular redaction box covers the majority of the page below the Ramsey County entry. Inside this box, the letters "(b) (4)" are printed in a large, light blue font.

(b) (4)

Stevens County/MN (2147308819)

(b) (4)

(b) (4)

## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2002 Wheat Field Test Report**  
USDA #02-046-17n                    Monsanto #2002-379XRAB

**September 19, 2003**

## **Biotech Field Compliance Team** **Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
2147303429	Polk	MN	
424036936	Ramsey	MN	
8025	Dakota	MN	Not Planted
2147308819	Stevens	MN	

**Polk County/MN (2147303429)**

**Planting Date:** 05/17/2002

**Destruct Date:** 07/23/2002

### **Vector Constructs/Line Numbers Planted: [CBI-Deleted]**

**Purpose of Field Trial:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

Ramsey County/MN (424036936)

**Planting Date:** 05/02/2002

**Harvest Date:** 08/07/2002

Destruct Date: 09/03/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

**Stevens County/MN (2147308819)**

**Planting Date:** 04/26/2002

**Harvest Date:** 08/08/2002

**Destruct Date:** 08/22/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

=====
 Bp number: 02-046-18n  
 =====

App number: 2002-382XRAB      Begin movement: 3/13/02  
 Received: 2/15/02      End movement: 3/13/03  
 Institution: Monsanto      Begin release: 3/13/02  
 Recipient: Wheat      End release: 3/13/03  
 Status: Pending      Acre: 3.00  
 Effective date: 3/17/02      CBI status: CBI  
 Phenotype: HT - Glyphosate tolerant  
 Comments:  
 Resp person: [REDACTED] (b) (6), (b) (7)(C)  
 Parsed name:  
 Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway N.  
 Address3:  
 Address4:  
 City/State/Zip: Chesterfield, MO 63198  
 Telephone: (b) (6), (b) (7)(C)      Fax: 636-737-7085  
 =====

- |  | Initial  | Date         |
|--|----------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ apd ]  | [ 2/21/02 ]  |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist               | [ DSH ]* | [ 2/21/02 ]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex  | [ KLN ]  | [ 2/21/02 ]* |
| 4. <input type="checkbox"/> State response                                     |          |              |

- | O/d                                    | Loc  | Site | Reg |      |         |             |     |
|--|--|------|-----|------|---------|-------------|-----|
| Interstate                             | *Dest*WA   | *    | *WR | *    | [ ]     | [ ]         |     |
| Interstate                             | *Orig*WA   | *    | *WR | *    | [ ]     | [ ]         |     |
| Release                                | *  | *WA  | *   | 1*WR | *       | [ ]         | [ ] |
| 5. <input checked="" type="checkbox"/> | Enter genes into database  |      |     |      | [ apd ] | [ 2/21/02 ] |     |
| 6. <input checked="" type="checkbox"/> | Letter of acknowledgement/denial/withdraw  |      |     |      | [ KLN ] | [ 3/7/02 ]* |     |
| 7. <input checked="" type="checkbox"/> | Enter final data into database   |      |     |      | [ KLN ] | [ 3/8/02 ]  |     |
| 8. <input type="checkbox"/>            | If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |      |     |      |         |             |     |



CONFIDENTIAL

**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-382XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 27037

02-046-18n

**1. USDA Reference Number**

2. Applicant Reference Number 2002-382XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)  
FAX 636/737-7085  
EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis MO 63198

**4. Duration of Introduction**

Interstate Movement and Release March 13, 2002 - March 13, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

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**Monsanto Reference ID**

2002-382XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/l2 --

(b) (4)

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/l5 --

(b) (4)

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

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**Monsanto Reference ID**

2002-382XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release500 pounds Ship up to 500 pounds wheat seed to and from each location.**ORIGIN:**

WA

**DESTINATION:**

WA

**Ship From:**

WA

\*[redacted] (b) (4) Whitman  
County/Province, WA, (b) (4) USACONTACT [redacted] (b) (4), (b) (6), (b) (7)(C)  
[redacted] (b) (4), (b) (6), (b) (7)(C) USA [redacted] (b) (4), (b) (6), (b) (7)(C)

] - CBI

\*[redacted] (b) (4) Lincoln County/Province, WA (b) (4)  
CONTACT [redacted] (b) (4), (b) (6), (b) (7)(C)  
[redacted] (b) (4), (b) (6), (b) (7)(C) USA [redacted] (b) (4), (b) (6), (b) (7)(C)

] - CBI

**Ship To:**

WA

\*[redacted] (b) (4) Whitman  
County/Province, WA, (b) (4) USA

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-382XRAB

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
[REDACTED] (b) (4), (b) (6), (b) (7)(C) USA [REDACTED]

] - CBI

\* [REDACTED] (b) (4) Lincoln County/Province, WA. (b) (4)  
(b) (4)

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
[REDACTED] (b) (4), (b) (6), (b) (7)(C) USA [REDACTED]

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-382XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

WA (1)

WA

[REDACTED] (b) (4) [REDACTED] Lincoln County/Province, WA (b) (4) 3  
acres. (b) (4) [REDACTED]

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) [REDACTED]  
(b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C) [REDACTED]

] - CBI

MONSANTO



CONFIDENTIAL

Monsanto Reference ID

2002-382XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C. Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C. Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costle, 622 F.2d 45, 51-52 (D.C. Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F. Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F. Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

#### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



**MONSANTO COMPANY**  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

*CBI-DELETED*

**Monsanto Reference ID**

2002-382XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-046-18n

**1. USDA Reference Number**

2. Applicant Reference Number 2002-382XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 636/737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 13, 2002 - March 13, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article****Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

# *CBI-DELETED*

**Monsanto Reference ID**

2002-382XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

*CBI-DELETED*

**Monsanto Reference ID**

2002-382XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

500 pounds Ship up to \_\_500\_\_\_\_ pounds wheat seed to and from each location.

**ORIGIN:**

WA

**DESTINATION:**

WA

**Ship From:**

WA

[ CBI Deleted ] -- \*Whitman County/Province, WA, USA

[ CBI Deleted ] -- \*Lincoln County/Province, WA, Lincoln

**Ship To:**

WA

[ CBI Deleted ] -- \*Whitman County/Province, WA, USA

*CBI-DELETED*

**Monsanto Reference ID**  
2002-382XRAB

[ CBI Deleted ] -- \*Lincoln County/Province, WA, Lincoln

*CBI-DELETED*

**Monsanto Reference ID**

2002-382XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

WA (1)

**WA**

[ CBI Deleted ] -- Lincoln County/Province, WA, Lincoln, 3 acres

MONSANTO



**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

*CBI-DELETED*

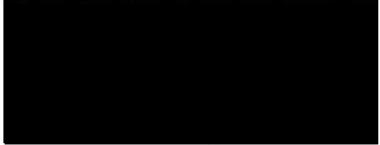
**Monsanto Reference ID**

2002-382XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
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**Monsanto Reference ID**

2002-382XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

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02-046-18n

**1. USDA Reference Number**

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FAX 636/737-7085  
Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis MO 63198

**4. Duration of Introduction**

Interstate Movement and Release

March 13, 2002 - March 13, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

**Monsanto Reference ID**

2002-382XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

**CBI**

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**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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**Monsanto Reference ID**

2002-382XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

500 pounds Ship up to \_\_500\_\_\_\_pounds wheat seed to and from each location.

**ORIGIN:**

WA

**DESTINATION:**

WA

**Ship From:**

WA

[ CBI Deleted ] -- \*Whitman County/Province, WA, USA

[ CBI Deleted ] -- \*Lincoln County/Province, WA, Lincoln

**Ship To:**

WA

[ CBI Deleted ] -- \*Whitman County/Province, WA, USA

**Monsanto Reference ID**  
2002-382XRAB

[ CBI Deleted ] -- \*Lincoln County/Province, WA, Lincoln

**Monsanto Reference ID**

2002-382XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

WA (1)

**WA**

[ CBI Deleted ] -- Lincoln County/Province, WA, Lincoln, 3 acres

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-382XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

February 20, 2002

Dear Mr. Wessels:

Enclosed is notification 02-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-046-18n	Applicant #:	2002-382XRAB
Received:	February 15, 2002	Effective:	March 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[S]

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009292



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

February 20, 2002

Dear Mr. Wessels:

Enclosed is notification 02-046-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-046-18n	Applicant #:	2002-382XRAB
Received:	February 15, 2002	Effective:	March 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/22/02

State: WA

Rptloc01/R4



APHIS • Protecting American Agriculture

An Equal Opportunity Employer

FEB 22 2002

OR120018\_BR\_009293

March 7, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 17, 2002.

Interstate movement and Release  
Notification no. 02-046-18n (2002-382XRAB)  
Regulated article - Wheat  
Destination - Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

cc:  
T. Wessels, Washington Dept. of Agric., Olympia, WA  
File number 02-046-18n

*CONFIDENTIAL*

**2002 Wheat Field Test Report**  
**USDA #02-046-18n**      **Monsanto #2002-382XRAB**

**September 19, 2003**

**Biotech Field Compliance Team**  
**Monsanto Company**

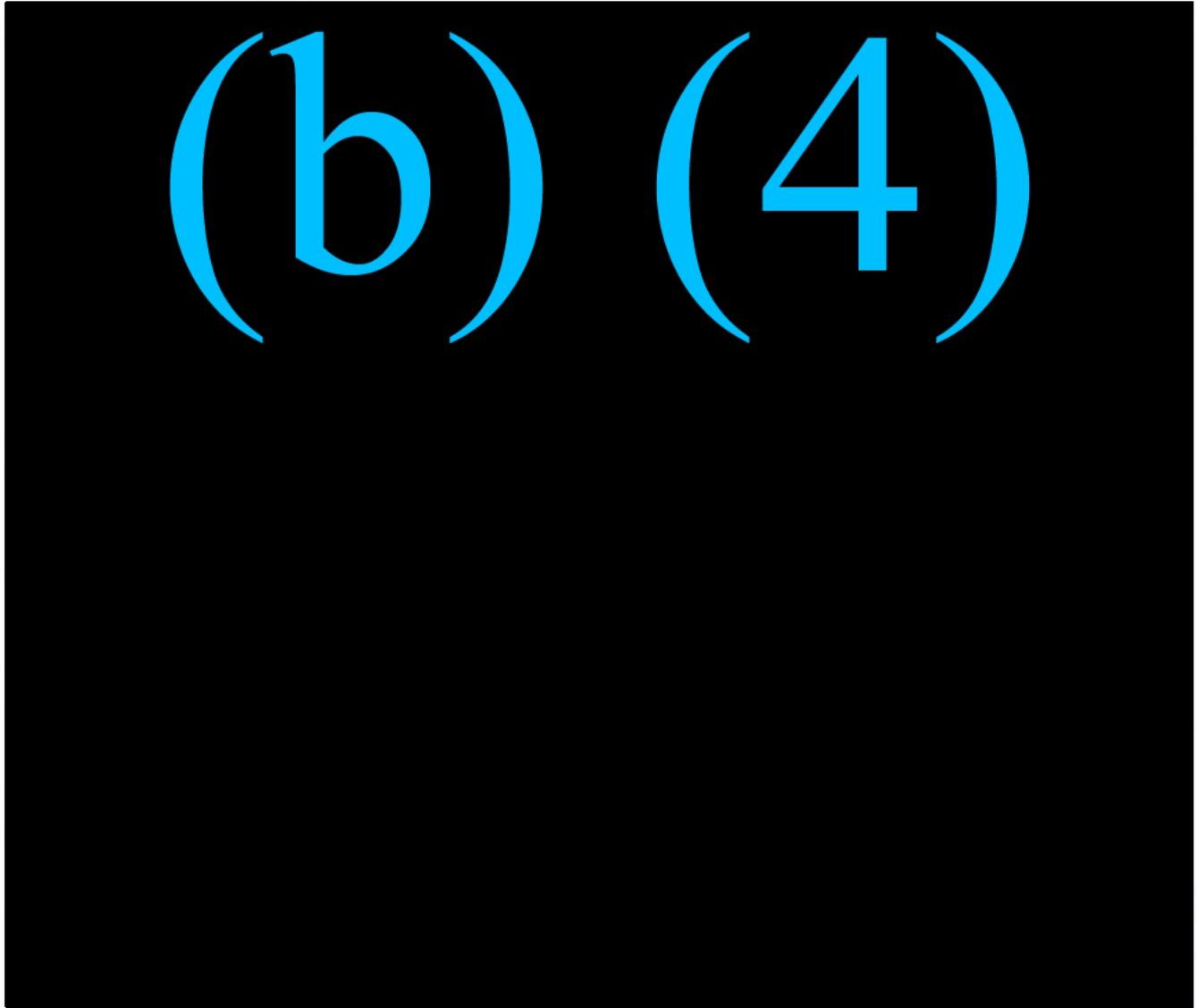
**Location**  
2147315629

**County**  
Lincoln

**State**  
WA

Lincoln County/WA (2147315629)

(b) (4)



## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

*CBI-DELETED*

**2002 Wheat Field Test Report  
USDA #02-046-18n                    Monsanto #2002-382XRAB**

**September 19, 2003**

**Biotech Field Compliance Team  
Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
2147315629	Lincoln	WA

**Lincoln County/WA (2147315629)**

**Planting Date:** 05/01/2002

**Harvest Date:** 08/23/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

=====
 Bp number: 02-046-27n
 =====

App number: 2002-410XRAB      Begin movement: 3/13/02  
 Received: 2/15/02      End movement: 3/13/03  
 Institution: Monsanto      Begin release: 3/13/02  
 Recipient: Wheat      End release: 3/13/03  
 Status: Pending      Acre: 7.00  
 Effective date: 3/17/02      CBI status: CBI  
 Phenotype: HT - Glyphosate tolerant  
 Comments:  
 Resp person: (b) (6), (b) (7)(C)  
 Parsed name:  
 Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway N.  
 Address3:  
 Address4:  
 City/State/Zip: Chesterfield, MO 63198  
 Telephone: (b) (6), (b) (7)(C)      Fax: 636-737-7085

=====

- |  | Initial  | Date          |
|--|----------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ apd ]  | [ 2/21/02 ]   |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist               | [ J ] *  | [ 2/21/02 ] * |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex  | [ KalN ] | [ 2/22/02 ] * |
| 4. <input type="checkbox"/> State response                                     |          |               |

O/d	Loc	Site	Reg			
Interstate	*Dest*MO	*	*SCR	*	[ ] [ ]	
Interstate	*Dest*SD	*	*SCR	*	[ ] [ ]	
Interstate	*Orig*MO	*	*SCR	*	[ ] [ ]	
Interstate	*Orig*SD	*	*SCR	*	[ ] [ ]	
Release	*	*SD	*	2*SCR	*	[ ] [ ]

- |  |          |              |
|--|----------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ apd ]  | [ 2/21/02 ]  |
| 6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw   | [ KalN ] | [ 3/7/02 ] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ KalN ] | [ 3/8/02 ]   |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |          |              |



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

CONFIDENTIAL

**Monsanto Reference ID**

2002-410XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-046-27n

**1. USDA Reference Number****2. Applicant Reference Number** 2002-410XRAB**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 636/737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 13, 2002 - March 13, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article****Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite and elite lines

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-410XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [REDACTED]

(b) (4)

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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**GENE OF INTEREST**

Promoter: CMP3/I5 -- [REDACTED]

(b) (4)

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# CONFIDENTIAL

**Monsanto Reference ID**

2002-410XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release2000 pounds Ship up to 2000 pounds wheat seed to and from each location.**ORIGIN:**

MO, SD

**DESTINATION:**

MO, SD

**Ship From:**

MO

\*[ (b) (4) St. Louis County/Province, MO (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4)

] - CBI

SD

\*[ (b) (4) SD County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)

] - CBI

\*[ (b) (4) Codington  
County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**  
2002-410XRAB

\*[ (b) (4) ] - CBI Brookings  
County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
SD USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

**Ship To:**

MO  
\*[ (b) (4) ] - CBI St. Louis County/Province, MO (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
USA (b) (4), (b) (6), (b) (7)(C) MO (b) (4)

] - CBI

SD  
\*[ (b) (4) ] - CBI SD County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
SD USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

\*[ (b) (4) ] - CBI Codington  
County/Province, SD, (b) (4) USA

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-410XRAB

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
SD [REDACTED] USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

\*[REDACTED] (b) (4) Brookings  
County/Province, SD, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
SD [REDACTED] USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-410XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

SD (2)

SD

[REDACTED] (b) (4) [REDACTED] Codington  
County/Province, SD, USA, 3 acres. (b) (4) [REDACTED]

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

[REDACTED] (b) (4) [REDACTED] Brookings  
County/Province, SD, USA, 4 acres. (b) (4) [REDACTED]

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



*CONFIDENTIAL*

**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Monsanto Reference ID

2002-410XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982)..

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organsim appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO



CBI-DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-410XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-046-27n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-410XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 13, 2002 - March 13, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:**

HT

**Phenotype:**

Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite and elite lines

# *CBI-DELETED*

**Monsanto Reference ID**

2002-410XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

*CBI-DELETED*

**Monsanto Reference ID**

2002-410XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

2000 pounds Ship up to \_\_2000\_\_\_\_pounds wheat seed to and from each location.

**ORIGIN:**

MO, SD

**DESTINATION:**

MO, SD

**Ship From:**

**MO**

[  CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**SD**

[  CBI Deleted ] -- \*SD County/Province, SD, USA

[  CBI Deleted ] -- \*Codington County/Province, SD, USA

**CBI-DELETED**

**Monsanto Reference ID**  
2002-410XRAB

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA

**Ship To:**

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**SD**

[ CBI Deleted ] -- \*SD County/Province, SD, USA

[ CBI Deleted ] -- \*Codington County/Province, SD, USA

*CBI-DELETED*

**Monsanto Reference ID**  
2002-410XRAB

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-410XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

SD (2)

**SD**

[ CBI Deleted ] -- Codington County/Province, SD, USA, 3 acres

[ CBI Deleted ] -- Brookings County/Province, SD, USA, 4 acres

MONSANTO



CBI-DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

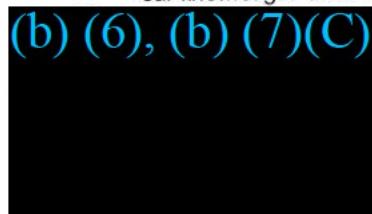
**Monsanto Reference ID**

2002-410XRAB

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(b) (6), (b) (7)(C)



Monsanto Company

MONSANTO



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**Monsanto Reference ID**

2002-410XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-046-27n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-410XRAB

**3. Applicant/Responsible Party**

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Phone

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FAX

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EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 13, 2002 - March 13, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite and elite lines

**Monsanto Reference ID**

2002-410XRAB

designation of transformed line:

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**GENE OF INTEREST**

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**CBI**

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**CBI**

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**Monsanto Reference ID**

2002-410XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

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**ORIGIN:**

MO, SD

**DESTINATION:**

MO, SD

**Ship From:**

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**SD**

[ CBI Deleted ] -- \*SD County/Province, SD, USA

[ CBI Deleted ] -- \*Codington County/Province, SD, USA

**Monsanto Reference ID**

2002-410XRAB

[  CBI Deleted ] -- \*Brookings County/Province, SD, USA

**Ship To:**

**MO**

[  CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**SD**

[  CBI Deleted ] -- \*SD County/Province, SD, USA

[  CBI Deleted ] -- \*Codington County/Province, SD, USA

**Monsanto Reference ID**

2002-410XRAB

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA

**Monsanto Reference ID**

2002-410XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

SD (2)

**SD**

[ CBI Deleted ] -- Codington County/Province, SD, USA, 3 acres

[ CBI Deleted ] -- Brookings County/Province, SD, USA, 4 acres

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-410XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 20, 2002

Dear Mr. Brown:

Enclosed is notification 02-046-27n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-046-27n	Applicant #:	2002-410XRAB
Received:	February 15, 2002	Effective:	March 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO SD		
Release destination:	SD		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009324

file copy

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

February 20, 2002

Dear Mr. Fridley:

Enclosed is notification 02-046-27n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-27n                      Applicant #: 2002-410XRAB  
Received: February 15, 2002                Effective: March 17, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: MO SD  
Release destination: SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009325



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 20, 2002

Dear Mr. Brown:

Enclosed is notification 02-046-27n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-27n                      Applicant #: 2002-410XRAB  
Received: February 15, 2002                Effective: March 17, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: MO SD  
Release destination: SD

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 02/27/02

State: MD

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 27 2002

OR120018\_BR\_009326



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

February 20, 2002



Dear Mr. Fridley:

Enclosed is notification 02-046-27n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-046-27n	Applicant #:	2002-410XRAB
Received:	February 15, 2002	Effective:	March 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: MO SD			
Release destination: SD			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoeck, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 2/25/02

State: South Dakota

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 25 2002

OR120018\_BR\_009327

March 7, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 17, 2002.

Interstate movement and Release  
Notification no. 02-046-27n (2002-410XRAB)  
Regulated article - Wheat  
Destinations - Missouri, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

cc:  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
K. Fridley, South Dakota Dept. of Agric., Pierre, SD  
File number 02-046-27n

MONSANTO



**CONFIDENTIAL**

April 26, 2002

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

Ms. Mary Jackson  
Animal and Plant Health Inspection Services  
Biotechnology and Scientific Services  
4700 River Road, Unit 147  
Riverdale, MD

Dear Ms. Jackson;

(b) (6), (b) (7)(C), (b) (4)

If you have any questions, please call at (b) (6), (b) (7)(C)

Sincerely /  
(b) (6), (b) (7)(C)

Cc: R. Stoaks, USDA, APHIS, PPQ, Fort Collins, CO  
K. Fridley, South Dakota Dept. of Agric. Pierre, SD

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

April 26, 2002

**CBI DELETED**

Ms. Mary Jackson  
Animal and Plant Health Inspection Services  
Biotechnology and Scientific Services  
4700 River Road, Unit 147  
Riverdale, MD

Dear Ms. Jackson;

In reviewing Monsanto acknowledged wheat notification it was discovered an error was given in the release information. The Monsanto number is 2002-410XRAB, USDA number 02-046-27n. The notification lists the release site [CBI deleted]  
It should be listed as [CBI deleted] [CBI deleted]. The acreage remains 4 acres. The responsible researcher remains [CBI deleted]

If you have any questions, please call at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

Cc: R. Stoaks, USDA, APHIS, PPQ, Fort Collins, CO  
K. Fridley, South Dakota Dept. of Agric. Pierre, SD

*Renewed 5/16/02*

## Biotechnology Inspection Manual

## Procedure

### SAMPLE NOTIFICATION FIELD SITE INSPECTION WORKSHEET

When completed, this is an Internal PPQ Document

APHIS Notification Number(s): (02 04/0 27n)

Applicant's Name: (b) (6), (b) (7)(C), (b) (4)

Crop: wheat

Name of Cooperator at Inspected Site: (b) (6), (b) (7)(C), (b) (4)

Trait/Gene: HT glyphosate

Location of Site: Brookings Co.

Phone: (b) (6), (b) (7)(C), (b) (4)

Type of Location: Farm  Nursery  Research  Other

(Describe) \_\_\_\_\_  
(b) (4)

GPS Coordinates (If available): Latitude (b) (4)

Longitude (b) (4)

Provide answers below. Circle "Y" for Yes and "N" for No. If the answer to any question is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

#### I. Shipping, Maintenance at Destination, and Identification

A. Did all aspects of field trial maintain identity (seed storage, planting-harvest site, borders, field cages, etc.)?

Y  N

B. Was a site map obtained or drawn by you for reference later? (For harvest, flower removal, volunteers, etc.)?

Y  N

#### II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants

A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop?

no other wheat  Y  N

B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located outside the pollination distance for the plants?

no compatible species  Y  N

C. Which of the five containment options is the applicant using? Check one below. If none, please note it here and state this in your cover letter to the Regional Program Manager.

- 1. Removing flowers.
  - C.1. Is there any evidence that the plants have flowers or that flowers have been removed?
- 2. Bagging flowers/tassels
  - C.2. Does the applicant have material to bag reproductive structures?
- 3. Terminating the experiment before flowering.
  - C.3. Were plants destroyed or removed from the field before any flowers were allowed to release pollen?
- 4. Physical isolation.
  - C.4. If there are any non-transgenic compatible plants within the distance stated in Table 1, were the non-transgenic plants within the pollination distances being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenics?
- 5. Temporal isolation.
  - C.5. Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap?

(b) (4)

OR120018\_BR\_009332

(b) (4)

OR120018\_BR\_009333

*CONFIDENTIAL*

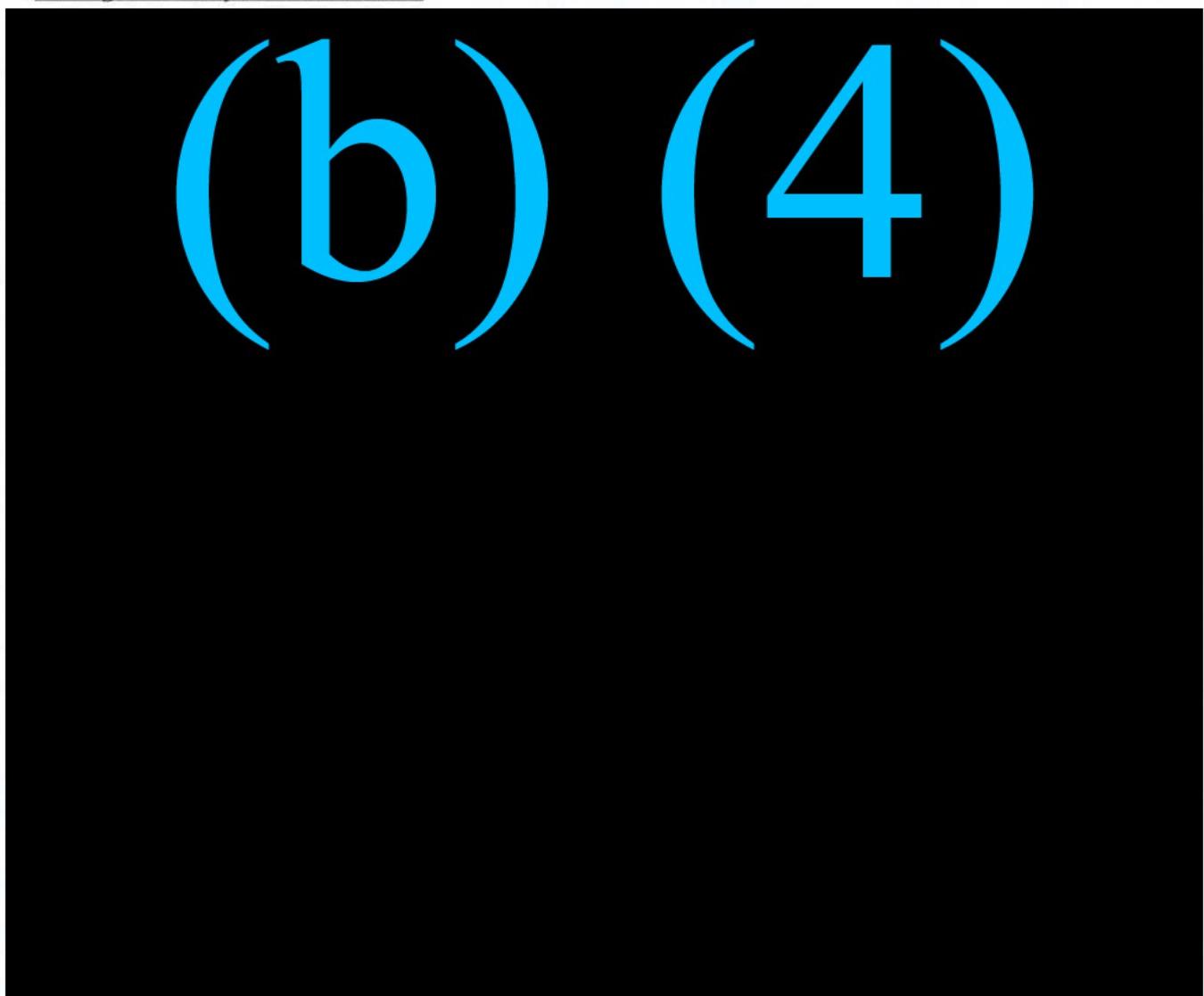
**2002 Wheat Field Test Report**  
**USDA #02-046-27n**      **Monsanto #2002-410XRAB**

**September 19, 2003**

**Biotech Field Compliance Team**  
**Monsanto Company**

<b>Location</b>	<b>County</b>	<b>State</b>
2147303325	Codington	SD
2147317546	Brookings	SD

Codington County/SD (2147303325)



(b) (4)

Brookings County/SD (2147317546)

(b) (4)

(b) (4)

## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

*CBI-DELETED*

**2002 Wheat Field Test Report**  
**USDA #02-046-27n**      **Monsanto #2002-410XRAB**

**September 19, 2003**

**Biotech Field Compliance Team**  
**Monsanto Company**

<b>Location</b>	<b>County</b>	<b>State</b>
2147303325	Codington	SD
2147317546	Brookings	SD

**Codington County/SD (2147303325)**

**Planting Date:** 05/14/2002

**Harvest Date:** 08/13/2002

**Destruct Date:** 08/13/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

**Brookings County/SD (2147317546)**

**Planting Date:** 05/16/2002

**Harvest Date:** 08/14/2002

**Destruct Date:** 08/14/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

=====  
 Bp number: 02-046-30n  
 =====

App number: 2002-417XRAB      Begin movement: 3/14/02  
 Received: 2/15/02      End movement: 3/14/03  
 Institution: Monsanto      Begin release: 3/14/02  
 Recipient: Wheat      End release: 3/14/03  
 Status: Pending      Acre: 10.00  
 Effective date: 3/17/02      CBI status: CBI  
 Phenotype: HT - Glyphosate tolerant  
 Comments:  
 Resp person: [REDACTED] (b) (6), (b) (7)(C)  
 Parsed name:  
 Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway N.  
 Address3:  
 Address4:  
 City/State/Zip: Chesterfield, MO 63198  
 Telephone: (b) (6), (b) (7)(C)      Fax: 636-737-7085

=====

- |  | Initial  | Date          |
|--|----------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ apd ]  | [ 2/21/02 ]   |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist               | [ J ] *  | [ 2/21/02 ] * |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex  | [ KLnD ] | [ 2/22/02 ] * |
| 4. <input type="checkbox"/> State response                                     |          |               |

O/d	Loc	Site	Reg			
Interstate	*Dest*KS	*	*SCR	*	[ ]	[ ]
Interstate	*Dest*MN	*	*NER	*	[ ]	[ ]
Interstate	*Dest*MO	*	*SCR	*	[ ]	[ ]
Interstate	*Dest*MT	*	*WR	*	[ ]	[ ]
Interstate	*Dest*ND	*	*SCR	*	[ ]	[ ]
Interstate	*Dest*SD	*	*SCR	*	[ ]	[ ]
Interstate	*Orig*KS	*	*SCR	*	[ ]	[ ]
Interstate	*Orig*MN	*	*NER	*	[ ]	[ ]
Interstate	*Orig*MO	*	*SCR	*	[ ]	[ ]
Interstate	*Orig*MT	*	*WR	*	[ ]	[ ]
Interstate	*Orig*ND	*	*SCR	*	[ ]	[ ]
Interstate	*Orig*SD	*	*SCR	*	[ ]	[ ]
Release	*	*ND	*	1*SCR	*	[ ]

- |  |          |               |
|--|----------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ apd ]  | [ 2/21/02 ]   |
| 6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw   | [ KLnD ] | [ 3/18/02 ] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ KLnD ] | [ 3/28/02 ]   |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |          |               |



CONFIDENTIAL

**MONSANTO COMPANY**  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-417XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-046-30n

**1. USDA Reference Number****2. Applicant Reference Number** 2002-417XRAB**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)  
FAX 636/737-7085  
EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis MO 63198

**4. Duration of Introduction**

Interstate Movement and Release March 14, 2002 - March 14, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article****Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar/variety Bobwhite

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**Monsanto Reference ID**

2002-417XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [REDACTED]

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [REDACTED]

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-417XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

A total of 1000 pounds of seed may be shipped for the term of this notification. Ship up to 500 pounds wheat seed to and from each location.

**ORIGIN:**

KS, MN, MO, MT, ND, SD

**DESTINATION:**

KS, MN, MO, MT, ND, SD

**Ship From:**

KS

\*[(b) (4)] Sedgwick County/Province, KS, (b) (4) USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] KS [(b) (4), (b) (6), (b) (7)(C)] USA,

] - CBI

MN

[(b) (4)] USA Ramsey County/Province, MN, (b) (4)

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] MN, [(b) (4), (b) (6), (b) (7)(C)] USA

] - CBI

MO

\*[(b) (4)] St. Louis County/Province, MO, (b) (4) USA

CONTACT: USA [(b) (4), (b) (6), (b) (7)(C)] (b) (4), (b) (6), (b) (7)(C) MO, [(b) (4), (b) (6), (b) (7)(C)]

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-417XRAB

MT

\*[ (b) (4) Gallatin County/Province, MT (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

ND

(b) (4) (b) (4) Foster County/Province, ND, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

\*[ (b) (4) Cass County/Province, ND (b) (4), U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A.

] - CBI

SD

(b) (4) (b) (4) Brookings County/Province, SD, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**  
2002-417XRAB

**Ship To:**

**KS**

\*[ (b) (4) Sedgwick County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4) USA,

] - CBI

**MN**

(b) (4) USA Ramsey County/Province, MN,

CONTACT: (b) (4), (b) (6), (b) (7)(C)

] - CBI

**MO**

[ (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4) USA

] - CBI

**MT**

[ (b) (4) Gallatin County/Province, MT, (b) (4) USA

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-417XRAB

CONTACT:  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b)  
MT, [REDACTED] USA,

] - CBI

**ND**

[REDACTED]  
**(b) (4)** U.S.A.

(b) (4)

Foster County/Province, ND,

CONTACT:  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND,

] - CBI

[REDACTED]

**(b) (4)**

Cass County/Province, ND, [REDACTED] (b) (4) U.S.A.

CONTACT:  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

ND,

] - CBI

**SD**

[REDACTED]  
**(b) (4)** USA

(b) (4)

Brookings County/Province, SD,

CONTACT:  
(b) (4), (b) (6), (b) (7)(C)

SD

(b) (4), (b) (6), (b) (7)(C)

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-417XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ND (1)

**ND**

[REDACTED] (b) (4) [REDACTED] Foster County/Province, ND,  
U.S.A., 10 acres. (b) (4) [REDACTED]

**RESPONSIBLE PERSON/RESEARCHER:** (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) ND [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Monsanto Reference ID

2002-417XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982)..

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, AgrEvo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

#### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organsim appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

CBI-DELETED

**Monsanto Reference ID**

2002-417XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-046-30n

**1. USDA Reference Number**

2. Applicant Reference Number 2002-417XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 14, 2002 - March 14, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar/variety Bobwhite

# CBI-DELETED

**Monsanto Reference ID**

2002-417XRAB

**designation of transformed line:** 33391**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

*CBI-DELETED*

**Monsanto Reference ID**

2002-417XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

A total of 1000 pounds of seed may be shipped for the term of this notification. Ship up to 500 pounds wheat seed to and from each location.

**ORIGIN:**

KS, MN, MO, MT, ND, SD

**DESTINATION:**

KS, MN, MO, MT, ND, SD

**Ship From:**

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**MN**

[ CBI Deleted ] -- \*Ramsey County/Province, MN, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-417XRAB

**MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**ND**

[ CBI Deleted ] -- \*Foster County/Province, ND, U.S.A.

[ CBI Deleted ] -- \*Cass County/Province, ND, U.S.A.

**SD**

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA

*CBI-DELETED*

**Monsanto Reference ID**  
2002-417XRAB

**Ship To:**

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**MN**

[ CBI Deleted ] -- \*Ramsey County/Province, MN, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

*CBI-DELETED*

**Monsanto Reference ID**  
2002-417XRAB

**ND**

[ CBI Deleted ] -- \*Foster County/Province, ND, U.S.A.

[ CBI Deleted ] -- \*Cass County/Province, ND, U.S.A.

**SD**

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-417XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ND (1)

**ND**

[ CBI Deleted ] -- Foster County/Province, ND, U.S.A., 10 acres

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

CBI-DELETED

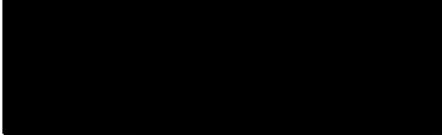
Monsanto Reference ID

2002-417XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-417XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-046-30n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-417XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 14, 2002 - March 14, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from cultivar/variety Bobwhite

**Monsanto Reference ID**

2002-417XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Monsanto Reference ID**

2002-417XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

A total of 1000 pounds of seed may be shipped for the term of this notification. Ship up to 500 pounds wheat seed to and from each location.

**ORIGIN:**

KS, MN, MO, MT, ND, SD

**DESTINATION:**

KS, MN, MO, MT, ND, SD

**Ship From:**

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**MN**

[ CBI Deleted ] -- \*Ramsey County/Province, MN, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Monsanto Reference ID**

2002-417XRAB

**MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**ND**

[ CBI Deleted ] -- \*Foster County/Province, ND, U.S.A.

[ CBI Deleted ] -- \*Cass County/Province, ND, U.S.A.

**SD**

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA

**Monsanto Reference ID**

2002-417XRAB

**Ship To:**

**KS**

[  CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**MN**

[  CBI Deleted ] -- \*Ramsey County/Province, MN, USA

**MO**

[  CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**MT**

[  CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**Monsanto Reference ID**

2002-417XRAB

**ND**

[ CBI Deleted ] -- \*Foster County/Province, ND, U.S.A.

[ CBI Deleted ] -- \*Cass County/Province, ND, U.S.A.

**SD**

[ CBI Deleted ] -- \*Brookings County/Province, SD, USA

**Monsanto Reference ID**

2002-417XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ND (1)

**ND**

[ CBI Deleted ] -- Foster County/Province, ND, U.S.A., 10 acres

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Monsanto Reference ID

2002-417XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

February 20, 2002

Dear Mr. Sim IV:

Enclosed is notification 02-046-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-30n                      Applicant #: 2002-417XRAB  
Received: February 15, 2002                Effective: March 17, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: KS MN MO MT ND SD  
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_009369

file copy

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

February 20, 2002

Dear Dr. Hanks:

Enclosed is notification 02-046-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-30n                      Applicant #: 2002-417XRAB  
Received: February 15, 2002                Effective: March 17, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: KS MN MO MT ND SD  
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009370

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 20, 2002

Dear Mr. Brown:

Enclosed is notification 02-046-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-30n                      Applicant #: 2002-417XRAB  
Received: February 15, 2002                Effective: March 17, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: KS MN MO MT ND SD  
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009371

file copy

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

February 20, 2002

Dear Mr. Ames:

Enclosed is notification 02-046-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-30n                      Applicant #: 2002-417XRAB  
Received: February 15, 2002                Effective: March 17, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: KS MN MO MT ND SD  
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009372

file copy

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

February 20, 2002

Dear Mr. Nelson:

Enclosed is notification 02-046-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-30n                      Applicant #: 2002-417XRAB  
Received: February 15, 2002                Effective: March 17, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: KS MN MO MT ND SD  
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009373

file copy

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

February 20, 2002

Dear Mr. Fridley:

Enclosed is notification 02-046-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-30n                      Applicant #: 2002-417XRAB  
Received: February 15, 2002                Effective: March 17, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: KS MN MO MT ND SD  
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009374



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

*faxed 2-27-02*

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

February 20, 2002

Dear Dr. Hanks:

Enclosed is notification 02-046-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-30n      Applicant #: 2002-417XRB  
Received: February 15, 2002      Effective: March 17, 2002  
Institution: Monsanto      Recipient: Wheat  
Interstate destination: KS MN MO MT ND SD  
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPO, Raleigh, NC

---

STATE RESPONSE TO NOTIFICATION

X

State concurs with APHIS determination. *Movement only*

\_\_\_\_\_ state DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 2-27-02

State: MN

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 27 2002

OR120018\_BR\_009375



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 20, 2002

Dear Mr. Brown:

Enclosed is notification 02-046-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-30n                      Applicant #: 2002-417XRAB  
Received: February 15, 2002                Effective: March 17, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: KS MN MO MT ND SD  
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

X

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 02/27/02

State: MD

Rptloc01/R4



APHIS - Protecting American Agriculture

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OR120018\_BR\_009376

FEB 27 2002



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

February 20, 2002

Dear Mr. Ames:

Enclosed is notification 02-046-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-30n                      Applicant #: 2002-417XRAB  
Received: February 15, 2002                Effective: March 17, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: KS MN MO MT ND SD  
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 2/25/02

State: Montana

Rptloc01/R4



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FEB 25 2002



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

*Releas*

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

February 20, 2002

Dear Mr. Nelson:

Enclosed is notification 02-046-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-30n                      Applicant #: 2002-417XRAB  
Received: February 15, 2002                Effective: March 17, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: KS MN MO MT ND SD  
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

*with attached conditions*

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Signature: *David R. Nelson*  
(b) (6), (b) (7)(C)

Date: 3-18-02

State: ND

Rptloc01/R4



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United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

Dear Mr. Fridley:

Enclosed is notification 02-046-30n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-046-30n      Applicant #: 2002-417XRAB  
 Received: February 15, 2002      Effective: March 17, 2002  
 Institution: Monsanto      Recipient: Wheat  
 Interstate destination: KS MN MO MT ND SD  
 Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
 Biotechnology Program Operations  
 Permits and Risk Assessments  
 Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: *Kevin Fridley*

Signature: (b) (6), (b) (7)(C)

Date: *2/25/02*

State: *South Dakota*

Rptloc01/R4



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An Equal Opportunity Employer

OR120018\_BR\_009379

FEB 25 2002



March 18, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 18, 2002.

**Interstate movement and Release**

**Notification no. 02-046-30n (2002-417XRAB)**

**Regulated article - Wheat**

**Destinations - Kansas, Minnesota, Missouri, Montana, North Dakota, South Dakota**

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota concurs with APHIS determination for movement only.

In addition, the State of North Dakota has (attached) modification of conditions for release of wheat.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN  
M. Brown, Missouri Dept of Agric., Jefferson City, MO  
G. Ames, Montana Dept. of Agric., Helena, MT  
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND  
K. Fridley, South Dakota Dept. of Agric., Pierre, SD  
File number 02-046-30n

AGRICULTURE COMMISSIONER  
ROGER JOHNSON



PHONE (701) 328-2231  
(800) 242-7535  
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE  
State of North Dakota  
600 E. Boulevard Ave. Dept. 602  
Bismarck, ND 58505-0020

TO: Mary Jackson  
Biotechnology Program Operations – Permit Unit  
USDA APHIS  
4700 River Road  
Riverdale MD 20703  
**(b) (6), (b) (7)(C)**

FROM: David R. Nelson

DATE: March 27, 2002

RE: Modification of Conditions for Release of Wheat  
02-022-59n  
02-051-19n  
02-046-30n  
02-022-57n

Following further discussions with Monsanto we are making a slight modification in the conditions for release of the wheat notifications listed above.

**North Dakota Supplemental Conditions 2002**

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers:
  - Wheat should not be grown within the field trial area nor within 33 feet of the field trial area during the subsequent growing season and any wheat volunteers appearing within this area should be destroyed prior to flowering.
  - If wheat grown for harvest as grain is grown within 330 feet of the field trial during the year of the field trial, then wheat intended for use as seed should not be grown within this area during the following year.

cc: Danny Gigax, Monsanto

OR120018\_BR\_009381

AGRICULTURE COMMISSIONER  
ROGER JOHNSON



PHONE (701) 328-2231  
(800) 242-7535  
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE  
State of North Dakota  
600 E. Boulevard Ave. Dept. 602  
Bismarck, ND 58505-0020

TO: Mary Jackson  
USDA-APHIS-PPQ  
Permits-Biotechnology  
4700 River Road  
Riverdale MD 20737  
**(b) (6), (b) (7)(C)**

FROM: David R. Nelson [REDACTED]

DATE: February 28, 2002

RE: Bp number 02-046-30n

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat appearing within this area should be destroyed.

OR120018\_BR\_009382

*CONFIDENTIAL*

**2002 Wheat Field Test Report**  
**USDA #02-046-30n**      **Monsanto #2002-417XRAB**

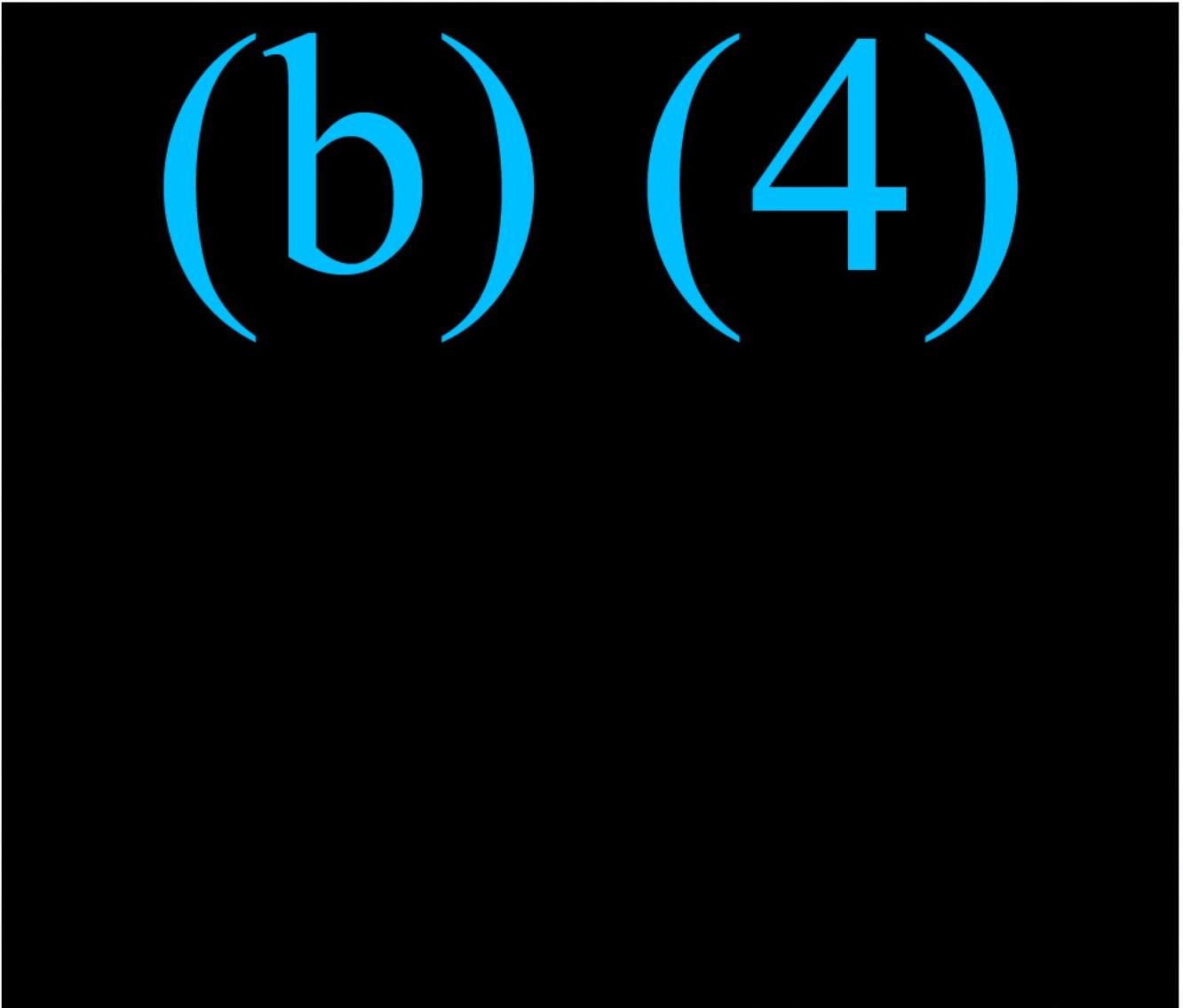
**September 19, 2003**

**Biotech Field Compliance Team**  
**Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
1611677957	Foster	ND

Foster County/ND (1611677957)

(b) (4)



(b) (4)

## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

*CBI-DELETED*

**2002 Wheat Field Test Report  
USDA #02-046-30n                    Monsanto #2002-417XRAB**

**September 19, 2003**

**Biotech Field Compliance Team  
Monsanto Company**

<b>Location</b>	<b>County</b>	<b>State</b>
1611677957	Foster	ND

**Foster County/ND (1611677957)**

**Planting Date:** 05/14/2002

**Destruct Date:** 07/31/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

=====  
 Bp number: 02-051-12n  
 =====

App number: 2002-424XRAB  
 Received: 2/20/02  
 Institution: Monsanto  
 Recipient: Wheat  
 Status: Pending  
 Effective date: 3/22/02  
 Phenotype: HT - Glyphosate tolerant  
 Comments:  
 Resp person: [REDACTED] (b) (6), (b) (7)(C)  
 Parsed name:  
 Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway N.  
 Address3:  
 Address4:  
 City/State/Zip: Chesterfield, MO 63198  
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085  
 =====

- |  | Initial | Date         |
|--|---------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ apd ] | [ 2/25/02 ]  |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist               | [ ]*    | [ 2/25/02 ]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex  | [ KLN ] | [ 2/26/02 ]* |
| 4. <input type="checkbox"/> State response                                     |         |              |

O/d	Loc	Site	Reg				
Interstate	*Dest*MO	*	*SCR	*	[ ]	[ ]	
Interstate	*Dest*MT	*	*WR	*	[ ]	[ ]	
Interstate	*Dest*WA	*	*WR	*	[ ]	[ ]	
Interstate	*Orig*MO	*	*SCR	*	[ ]	[ ]	
Interstate	*Orig*MT	*	*WR	*	[ ]	[ ]	
Interstate	*Orig*WA	*	*WR	*	[ ]	[ ]	
Release	*	*MT	*	5*WR	*	[ ]	[ ]
Release	*	*WA	*	1*WR	*	[ ]	[ ]

- |  |         |              |
|--|---------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ apd ] | [ 2/25/02 ]  |
| 6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw   | [ KLN ] | [ 3/19/02 ]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ KLN ] | [ 3/20/02 ]  |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |         |              |



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

CONFIDENTIAL

**Monsanto Reference ID**

2002-424XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-051-12n

**1. USDA Reference Number****2. Applicant Reference Number** 2002-424XRAB**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 16, 2002 - March 16, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article****Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite and elite lines

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-424XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- I

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

# CONFIDENTIAL

**Monsanto Reference ID**

2002-424XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

10,000 pounds Ship up to 10,000 pounds wheat seed to and from each location.

**ORIGIN:**

MO, MT, WA

**DESTINATION:**

MO, MT, WA

**Ship From:**

MO

\*[REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] MO, 63198,  
USA, [REDACTED]

] - CBI

MT

\*[REDACTED] (b) (4) Fergus County/Province, MT, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] MT, [REDACTED] USA,  
(b) (4), (b) (6), (b) (7)(C)

] - CBI

\*[REDACTED] (b) (4), (b) (6), (b) (7)(C) Teton County/Province, MT, [REDACTED] USA  
[REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] USA, [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] USA,

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**  
2002-424XRAB

\*[ (b) (4) ] - CBI Montana County/Province, MT [ (b) (4) ] USA

CONTACT: [ (b) (4), (b) (6), (b) (7)(C) ] Bozeman, MT, [ (b) (4), (b) (6), (b) (7)(C) ] USA,

] - CBI

\*[ (b) (4), (b) (6), (b) (7)(C) ] Gallatin County/Province, MT, [ (b) (4), (b) (6), (b) (7)(C) ] USA

CONTACT: [ (b) (4), (b) (6), (b) (7)(C) ] MT, [ (b) (4), (b) (6), (b) (7)(C) ] USA,

] - CBI

\*[ (b) (4) ] - CBI Gallatin County/Province, MT, [ (b) (4) ] USA

CONTACT: [ (b) (4), (b) (6), (b) (7)(C) ] MT, [ (b) (4), (b) (6), (b) (7)(C) ] USA,

] - CBI

\*[ (b) (4) ] - CBI Montana County/Province, MT, [ (b) (4) ] Park

CONTACT: [ (b) (4), (b) (6), (b) (7)(C) ] MT, [ (b) (4), (b) (6), (b) (7)(C) ] USA,

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**  
2002-424XRAB

\* [REDACTED] (b) (4) Gallatin County/Province, MT (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] MT, [REDACTED] (b) (4), USA,

] - CBI

\*[REDACTED] (b) (4) Montana County/Province, MT (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] MT,

] - CBI

WA

\*[REDACTED] (b) (4) Walla Walla County/Province, WA (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] MT, [REDACTED] (b) (4), USA,

] - CBI

**Ship To:**

MO

\*[REDACTED] (b) (4) St. Louis County/Province, MO (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] MO, [REDACTED] (b) (4), USA,

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-424XRAB

MT

(b) (4)

Fergus County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MT, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

\*[(b) (4), (b) (6), (b) (7)(C)] Teton County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MT, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

\*[(b) (4)] Montana County/Province, MT, (b) (4) USA

CONTACT: USA (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MT, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

\*[(b) (4), (b) (6), (b) (7)(C)] Gallatin County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MT, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**  
2002-424XRAB

\* [REDACTED] (b) (4) Gallatin County/Province, MT (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
USA, [REDACTED] (b) (4), (b) (6), (b) (7)(C) MT, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

\* [REDACTED] (b) (4) Montana County/Province, MT (b) (4) Park

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

\* [REDACTED] (b) (4) Gallatin County/Province, MT (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

\* [REDACTED] (b) (4) Montana County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MT,

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-424XRAB

WA

\* [REDACTED] (b) (4) Walla Walla County/Province, WA (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) [REDACTED] MT, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-424XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT (5), WA (1)

**MT**

(b) (4)

Fergus County/Province, MT, USA, 3 acres.

(b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C) Teton County/Province, MT, USA, 6 acres. (b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4)

Montana County/Province, MT, USA, 4 acres.

(b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C) , Gallatin County/Province, MT, USA, 8 acres. (b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**  
2002-424XRAB

[REDACTED] (b) (4) [REDACTED] Montana County/Province, MT, USA, 3  
acres. [REDACTED] (b) (4) [REDACTED]

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED]  
(b) (4), (b) (6), (b) (7)(C) MT [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED]

] - CBI

**WA**

(b) (4) [REDACTED] Walla Walla County/Province, WA, USA, 3 acres. [REDACTED] (b) (4) [REDACTED]

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED]  
(b) (4), (b) (6), (b) (7)(C) MT [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED]

] - CBI

MONSANTO



**MONSANTO COMPANY**

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**CONFIDENTIAL**

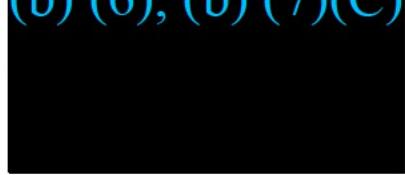
**Monsanto Reference ID**

2002-424XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C. Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C. Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982)..

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costle, 622 F.2d 45, 51-52 (D.C. Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F. Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F. Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

#### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

#### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

CBI-DELETED

**Monsanto Reference ID**

2002-424XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-051-12n

**1. USDA Reference Number****2. Applicant Reference Number** 2002-424XRAB**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 16, 2002 - March 16, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article****Phenotypic Category:**

HT

**Phenotype:**

Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite and elite lines

# *CBI-DELETED*

**Monsanto Reference ID**

2002-424XRAB

**designation of transformed line:** 33391**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

*CBI-DELETED*

**Monsanto Reference ID**

2002-424XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

10,000 pounds Ship up to \_10,000\_\_\_\_\_ pounds wheat seed to and from each location.

**ORIGIN:**

MO, MT, WA

**DESTINATION:**

MO, MT, WA

**Ship From:**

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**MT**

[ CBI Deleted ] -- \*Fergus County/Province, MT, USA

[ CBI Deleted ] -- \*Teton County/Province, MT, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-424XRAB

[ CBI Deleted ] -- \*Montana County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Montana County/Province, MT, Park

*CBI-DELETED*

**Monsanto Reference ID**

2002-424XRAB

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Montana County/Province, MT, USA

**WA**

[ CBI Deleted ] -- \*Walla Walla County/Province, WA, USA

**Ship To:**

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-424XRAB

**MT**

[ CBI Deleted ] -- \*Fergus County/Province, MT, USA

[ CBI Deleted ] -- \*Teton County/Province, MT, USA

[ CBI Deleted ] -- \*Montana County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-424XRAB

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Montana County/Province, MT, Park

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Montana County/Province, MT, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-424XRAB

**WA**

[ CBI Deleted ] -- \*Walla Walla County/Province, WA, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-424XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT (5), WA (1)

**MT**

[ CBI Deleted ] -- Fergus County/Province, MT, USA, 3 acres

[ CBI Deleted ] -- Teton County/Province, MT, USA, 6 acres

[ CBI Deleted ] -- Montana County/Province, MT, USA, 4 acres

[ CBI Deleted ] -- Gallatin County/Province, MT, USA, 8 acres

*CBI-DELETED*

**Monsanto Reference ID**

2002-424XRAB

[ CBI Deleted ] -- Montana County/Province, MT, USA, 3 acres

**WA**

[ CBI Deleted ] -- Walla Walla County/Province, WA, USA, 3 acres

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

*CBI-DELETED*

Monsanto Reference ID

2002-424XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

MONSANTO



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700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**

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Permit Unit

USDA, APHIS, PPQ, BSS

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Riverdale, MD 27037

02-051-12n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-424XRAB

**3. Applicant/Responsible Party**

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Phone (b) (6), (b) (7)(C)

FAX 636/737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 16, 2002 - March 16, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite and elite lines

**Monsanto Reference ID**

2002-424XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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2002-424XRAB

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**ORIGIN:**

MO, MT, WA

**DESTINATION:**

MO, MT, WA

**Ship From:**

MO

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

MT

[ CBI Deleted ] -- \*Fergus County/Province, MT, USA

[ CBI Deleted ] -- \*Teton County/Province, MT, USA

**Monsanto Reference ID**

2002-424XRAB

[ CBI Deleted ] -- \*Montana County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Montana County/Province, MT, Park

**Monsanto Reference ID**

2002-424XRAB

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Montana County/Province, MT, USA

**WA**

[ CBI Deleted ] -- \*Walla Walla County/Province, WA, USA

**Ship To:**

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Monsanto Reference ID**

2002-424XRAB

**MT**

[ CBI Deleted ] -- \*Fergus County/Province, MT, USA

[ CBI Deleted ] -- \*Teton County/Province, MT, USA

[ CBI Deleted ] -- \*Montana County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**Monsanto Reference ID**

2002-424XRAB

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Montana County/Province, MT, Park

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Montana County/Province, MT, USA

**Monsanto Reference ID**

2002-424XRAB

**WA**

[ CBI Deleted ] -- \*Walla Walla County/Province, WA, USA

**Monsanto Reference ID**

2002-424XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT (5), WA (1)

**MT**

[ CBI Deleted ] -- Fergus County/Province, MT, USA, 3 acres

[ CBI Deleted ] -- Teton County/Province, MT, USA, 6 acres

[ CBI Deleted ] -- Montana County/Province, MT, USA, 4 acres

[ CBI Deleted ] -- Gallatin County/Province, MT, USA, 8 acres

**Monsanto Reference ID**

2002-424XRAB

[ CBI Deleted ] -- Montana County/Province, MT, USA, 3 acres

**WA**

[ CBI Deleted ] -- Walla Walla County/Province, WA, USA, 3 acres

MONSANTO



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700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

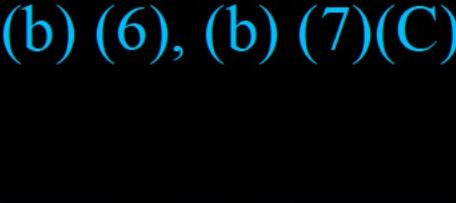
**Monsanto Reference ID**

2002-424XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 22, 2002

Dear Mr. Brown:

Enclosed is notification 02-051-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-051-12n	Applicant #:	2002-424XRAB
Received:	February 20, 2002	Effective:	March 22, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT WA		
Release destination:	MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[S]

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009425

file copy

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

February 22, 2002

Dear Mr. Ames:

Enclosed is notification 02-051-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-051-12n                      Applicant #: 2002-424XRAB  
Received: February 20, 2002                Effective: March 22, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: MO MT WA  
Release destination: MT WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[S]

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009426

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

February 22, 2002

Dear Mr. Wessels:

Enclosed is notification 02-051-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-051-12n	Applicant #:	2002-424XRAB
Received:	February 20, 2002	Effective:	March 22, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT WA		
Release destination:	MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009427



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 22, 2002

Dear Mr. Brown:

Enclosed is notification 02-051-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-051-12n      Applicant #: 2002-424XRAB  
Received: February 20, 2002      Effective: March 22, 2002  
Institution: Monsanto      Recipient: Wheat  
Interstate destination: MO MT WA  
Release destination: MT WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

*Michael E. Brown*

Signature:

(b) (6), (b) (7)(C)

Date: 02/28/02

State: MO

Rptloc01/R4



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OR120018\_BR\_009428

MAR 1 2002



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

February 22, 2002

Dear Mr. Ames:

Enclosed is notification 02-051-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-051-12n                      Applicant #: 2002-424XRAB  
Received: February 20, 2002                Effective: March 22, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: MO MT WA  
Release destination: MT WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 2/27/02

State: Montana

Rptlcc01/R4



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An Equal Opportunity Employer

OR120018\_BR\_009429

FEB 27 2002



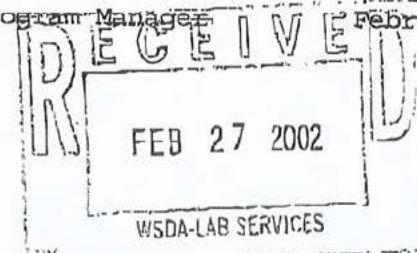
United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

February 22, 2002



Dear Mr. Wessels:

Enclosed is notification 02-051-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-051-12n	Applicant #:	2002-424XRAB
Received:	February 20, 2002	Effective:	March 22, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: MO MT WA			
Release destination: MT WA			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/28/02

State: WA

Rptloc01/R4



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An Equal Opportunity Employer

OR120018\_BR\_009430

FEB 28 2002

March 19, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 22, 2002.

**Interstate movement and Release**

Notification no. 02-051-12n (2002-424XRAB)

Regulated article - Wheat

Destinations - Missouri, Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
G. Ames, Montana Dept. of Agric., Helena, MT  
T. Wessels, Washington Dept. of Agric., Olympia, WA  
File number 02-051-12n

# Confirmation Report-Memory Send

Time : Mar-19-02 04:40pm  
Tel line 1 :  
Tel line 2 :  
Name :

Job number : 047  
Date : Mar-19 04:39pm  
To : 916367377085  
Document Pages : 01  
Start time : Mar-19 04:39pm  
End time : Mar-19 04:40pm  
Pages sent : 01

Job number : 047

\*\*\* SEND SUCCESSFUL \*\*\*



Animal and  
Plant Health  
Inspection Service

Permits &  
Risk  
Assessments

1700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

MARCH 19, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 22, 2002.

Interstate movement and Release  
Notification no. 02-051-12n (2002-424XRAB)  
Regulated article - Wheat  
Destinations - Missouri, Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgement does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving state Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

CC:  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
G. Ames, Montana Dept. of Agric., Helena, MT  
T. Wessels, Washington Dept. of Agric., Olympia, WA



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An Equal Opportunity Employer

OR120018\_BR\_009432

*CONFIDENTIAL*

**2002 Wheat Field Test Report**  
**USDA #02-051-12n**      **Monsanto #2002-424XRAB**

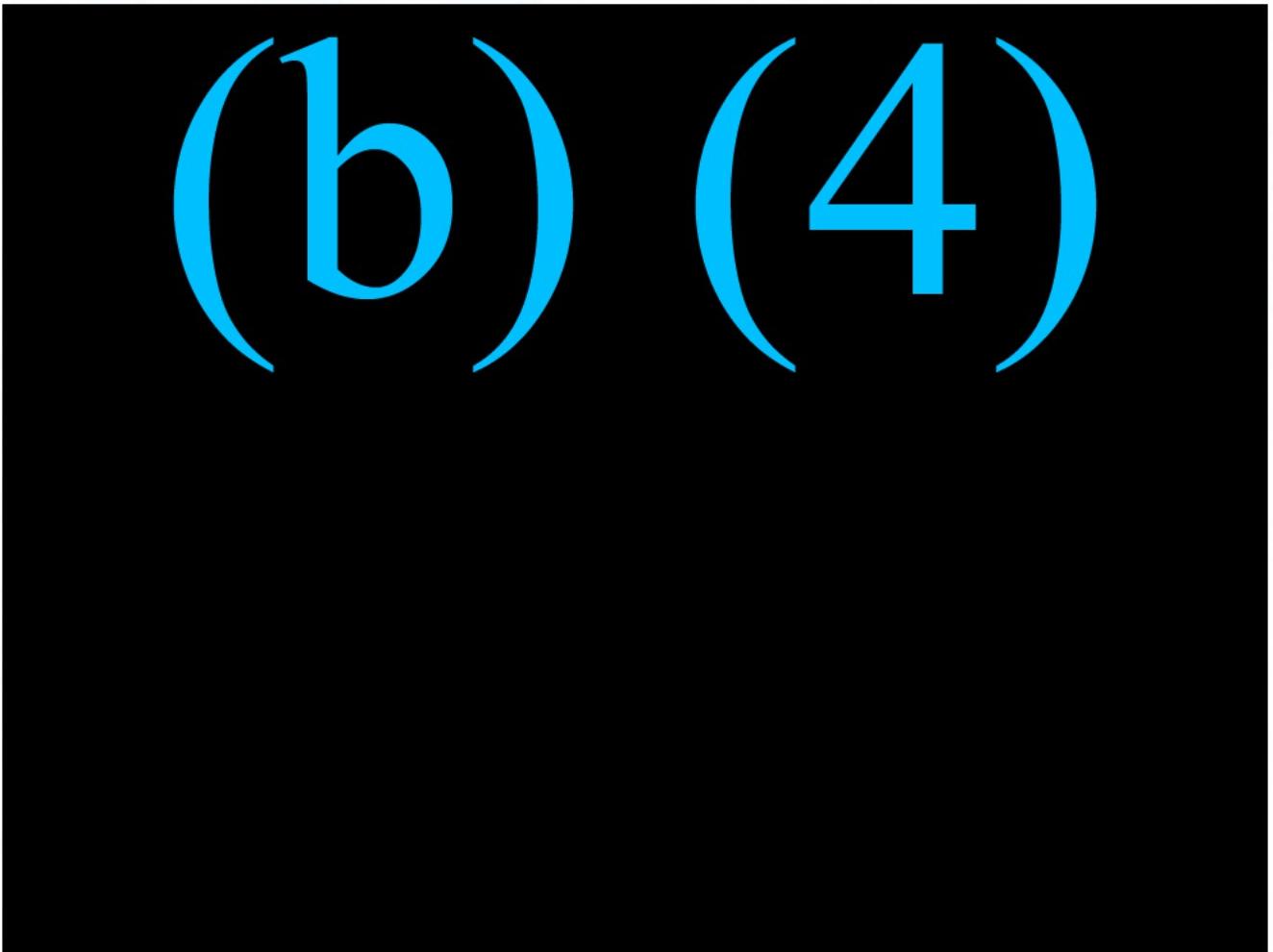
**September 19, 2003**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>
2147315700	Fergus	MT
2147315696	Teton	MT
2147315697	Montana	MT
2147308221	Gallatin	MT
2147315698	Montana	MT
2147308222	Walla Walla	WA

Fergus County/MT (2147315700)

(b) (4)



(b) (4)

Teton County/MT (2147315696)

(b) (4)

(b) (4)

Gallatin County/MT (2147308221)

(b) (4)

(b) (4)

## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

*CBI-DELETED*

**2002 Wheat Field Test Report  
USDA #02-051-12n                    Monsanto #2002-424XRAB**

**September 19, 2003**

**Biotech Field Compliance Team  
Monsanto Company**

<b>Location</b>	<b>County</b>	<b>State</b>	
2147315700	Fergus	MT	
2147315696	Teton	MT	
2147315697	Montana	MT	Not Planted
2147308221	Gallatin	MT	
2147315698	Montana	MT	Not Planted
2147308222	Walla Walla	WA	Not Planted

**Fergus County/MT (2147315700)**

**Planting Date:** 05/02/2002

**Harvest Date:** 08/20/2002

**Destruct Date:** 09/27/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

**Teton County/MT (2147315696)**

**Planting Date:** 05/04/2002

**Harvest Date:** 09/14/2002

**Destruct Date:** 09/16/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

**Gallatin County/MT (2147308221)**

**Planting Date:** 05/17/2002

**Harvest Date:** 09/16/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

2/22/02 11:39 am

## Notification Tracking Sheet

=====
 Bp number: 02-051-19n  
 =====

App number: 2002-457XRAB                      Begin movement: 3/20/02  
 Received: 2/20/02                              End movement: 3/20/03  
 Institution: Monsanto                            Begin release: 3/20/02  
 Recipient: Wheat                                End release: 3/20/03  
 Status: Pending                                Acre: 14.00  
 Effective date: 3/22/02                        CBI status: CBI  
 Phenotype: HT - Glyphosate tolerant  
 Comments:  
 Resp person: [REDACTED] (b) (6), (b) (7)(C)  
 Parsed name:  
 Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway N.  
 Address3:  
 Address4:  
 City/State/Zip: Chesterfield, MO 63198  
 Telephone: (b) (6), (b) (7)(C)                      Fax: 636-737-7085

=====

		Initial	Date
1.	[ <input checked="" type="checkbox"/> ] Assign Bp number and initial data entry	[ajd]	[2/25/02]
2.	[ <input checked="" type="checkbox"/> ] Review by biotechnologist	[ ]*	[2/25/02]*
3.	[ <input checked="" type="checkbox"/> ] Letter of notification to State Fed-ex	[KLN]	[2/27/02]*
4.	[ <input type="checkbox"/> ] State response		

O/d	Loc	Site	Reg		
Interstate	*Dest*MO	*	*SCR *	[ ]	[ ]
Interstate	*Dest*ND	*	*SCR *	[ ]	[ ]
Interstate	*Orig*MO	*	*SCR *	[ ]	[ ]
Interstate	*Orig*ND	*	*SCR *	[ ]	[ ]
Release	*	*ND	*	[ ]	[ ]
5.	[ <input checked="" type="checkbox"/> ] Enter genes into database	[OD]	[2/25/02]		
6.	[ <input checked="" type="checkbox"/> ] Letter of acknowledgement/denial/withdraw	[KLN]	[3/21/02]*		
7.	[ <input checked="" type="checkbox"/> ] Enter final data into database	[KLN]	[3/28/02]		
8.	[ <input type="checkbox"/> ] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify				



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63108  
<http://www.monsanto.com>

CONFIDENTIAL

**Monsanto Reference ID**

2002-457XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-051-19n

**1. USDA Reference Number**

2. Applicant Reference Number 2002-457XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 20, 2002 - March 20, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

# CONFIDENTIAL

**Monsanto Reference ID**

2002-457XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVaII2 -- I

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- I

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

# CONFIDENTIAL

**Monsanto Reference ID**

2002-457XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

2000 pounds Ship up to \_2000\_\_\_\_\_ pounds wheat seed to and from each location.

**ORIGIN:**

MO, ND

**DESTINATION:**

MO, ND

**Ship From:**

MO

\*[REDACTED] (b) (4) St. Louis County/Province, MO (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, [REDACTED]  
USA, [REDACTED]

] - CBI

ND

\*[REDACTED] (b) (4) Cass County/Province, ND (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) ND, [REDACTED] USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

\*[REDACTED] (b) (4) Foster County/Province, ND,  
(b) (4) U.S.A.CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) ND, [REDACTED] USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**  
2002-457XRAB

\*[ (b) (4) ] - CBI Ward County/Province, ND (b) (4)  
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

\*[ (b) (4) ] - CBI Cavalier  
County/Province, ND (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

\*[ (b) (4) ] - CBI Cass County/Province,  
ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

**Ship To:**

MO  
\*[ (b) (4) ] - CBI St. Louis County/Province, MO (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO (b) (4), (b) (6), (b) (7)(C)  
USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-457XRAB

ND

(b) (4)

Cass County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

(b) (4) U.S.A.

(b) (4)

Foster County/Province, ND,

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

U.S.A.

(b) (4)

Ward County/Province, ND, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

\*[ County/Province, ND, (b) (4) USA

(b) (4)

Cavalier

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

*CONFIDENTIAL*

**Monsanto Reference ID**  
2002-457XRAB

\*[REDACTED] (b) (4) [REDACTED] Fargo, Cass County/Province,  
ND (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) ND [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-457XRAB

Release Site:

**NUMBER OF STATES/TERRITORIES AND SITES:**

ND (4)

ND

(b) (4)

Cass County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)  
ND<sup>(b) (4), (b) (6), (b) (7)(C)</sup> USA<sup>(b) (4), (b) (6), (b) (7)(C)</sup>

] - CBI

[ (b) (4)  
U.S.A., 3 acres. (b) (4)

Foster County/Province, ND,

RESPONSIBLE PERSON/RESEARCHER:  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)  
ND<sup>(b) (4), (b) (6), (b) (7)(C)</sup> USA<sup>(b) (4), (b) (6), (b) (7)(C)</sup>

] - CBI

[ (b) (4)  
acres. (b) (4)

Ward County/Province, ND, U.S.A., 3

RESPONSIBLE PERSON/RESEARCHER:  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)  
ND<sup>(b) (4), (b) (6), (b) (7)(C)</sup> USA<sup>(b) (4), (b) (6), (b) (7)(C)</sup>

] - CBI

[ (b) (4)  
County/Province, ND, USA, 3 acres. (b) (4)

Cavalier

RESPONSIBLE PERSON/RESEARCHER:  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)  
ND<sup>(b) (4), (b) (6), (b) (7)(C)</sup> USA<sup>(b) (4), (b) (6), (b) (7)(C)</sup>

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-457XRAB

] - CBI

MONSANTO



*CONFIDENTIAL*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

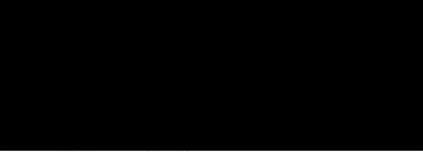
Monsanto Reference ID

2002-457XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982)..

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

#### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63108  
<http://www.monsanto.com>

CBI-DELETED

**Monsanto Reference ID**

2002-457XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-051-19n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-457XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)[monsanto.com](mailto:monsanto.com)

Monsanto Company

700 Chesterfield Parkway North  
St. Louis MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 20, 2002 - March 20, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

# *CBI-DELETED*

**Monsanto Reference ID**

2002-457XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

*CBI-DELETED*

**Monsanto Reference ID**

2002-457XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

2000 pounds Ship up to \_2000\_\_\_\_\_pounds wheat seed to and from each location.

**ORIGIN:**

MO, ND

**DESTINATION:**

MO, ND

**Ship From:**

MO

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

ND

[ CBI Deleted ] -- \*Cass County/Province, ND, USA

[ CBI Deleted ] -- \*Foster County/Province, ND, U.S.A.

*CBI-DELETED*

**Monsanto Reference ID**  
2002-457XRAB

[ CBI Deleted ] -- \*Ward County/Province, ND, U.S.A.

[ CBI Deleted ] -- \*Cavalier County/Province, ND, USA

[ CBI Deleted ] -- \*Cass County/Province, ND, USA

**Ship To:**

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-457XRAB

**ND**

[ CBI Deleted ] -- \*Cass County/Province, ND, USA

[ CBI Deleted ] -- \*Foster County/Province, ND, U.S.A.

[ CBI Deleted ] -- \*Ward County/Province, ND, U.S.A.

[ CBI Deleted ] -- \*Cavalier County/Province, ND, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-457XRAB

[ CBI Deleted ] -- \*Cass County/Province, ND, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-457XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (4)

**ND**

[ CBI Deleted ] -- Cass County/Province, ND, USA, 5 acres

[ CBI Deleted ] -- Foster County/Province, ND, U.S.A., 3 acres

[ CBI Deleted ] -- Ward County/Province, ND, U.S.A., 3 acres

[ CBI Deleted ] -- Cavalier County/Province, ND, USA, 3 acres

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

*CBI-DELETED*

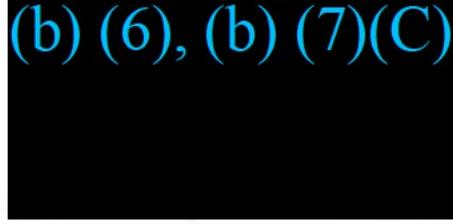
Monsanto Reference ID

2002-457XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-457XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-051-19n

- 1. USDA Reference Number**
- 2. Applicant Reference Number** 2002-457XRAB
- 3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)  
FAX 636/737-7085  
EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis MO 63198

**4. Duration of Introduction**

Interstate Movement and Release

March 20, 2002 - March 20, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

**Monsanto Reference ID**

2002-457XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

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**Monsanto Reference ID**

2002-457XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

2000 pounds Ship up to \_2000\_\_\_\_\_pounds wheat seed to and from each location.

**ORIGIN:**

MO, ND

**DESTINATION:**

MO, ND

**Ship From:**

MO

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

ND

[ CBI Deleted ] -- \*Cass County/Province, ND, USA

[ CBI Deleted ] -- \*Foster County/Province, ND, U.S.A.

**Monsanto Reference ID**

2002-457XRAB

[ CBI Deleted ] -- \*Ward County/Province, ND, U.S.A.

[ CBI Deleted ] -- \*Cavalier County/Province, ND, USA

[ CBI Deleted ] -- \*Cass County/Province, ND, USA

**Ship To:**

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Monsanto Reference ID**

2002-457XRAB

**ND**

[ CBI Deleted ] -- \*Cass County/Province, ND, USA

[ CBI Deleted ] -- \*Foster County/Province, ND, U.S.A.

[ CBI Deleted ] -- \*Ward County/Province, ND, U.S.A.

[ CBI Deleted ] -- \*Cavalier County/Province, ND, USA

**Monsanto Reference ID**  
2002-457XRAB

[ CBI Deleted ] -- \*Cass County/Province, ND, USA

**Monsanto Reference ID**

2002-457XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ND (4)

**ND**

[ CBI Deleted ] -- Cass County/Province, ND, USA, 5 acres

[ CBI Deleted ] -- Foster County/Province, ND, U.S.A., 3 acres

[ CBI Deleted ] -- Ward County/Province, ND, U.S.A., 3 acres

[ CBI Deleted ] -- Cavalier County/Province, ND, USA, 3 acres

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

OR120018\_BR\_009470

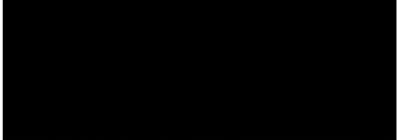
Monsanto Reference ID

2002-457XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 22, 2002

Dear Mr. Brown:

Enclosed is notification 02-051-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-051-19n	Applicant #:	2002-457XRAB
Received:	February 20, 2002	Effective:	March 22, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[Signature]

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009471

file copy

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

February 22, 2002

Dear Mr. Nelson:

Enclosed is notification 02-051-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-051-19n	Applicant #:	2002-457XRAB
Received:	February 20, 2002	Effective:	March 22, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009472



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 22, 2002

Dear Mr. Brown:

Enclosed is notification 02-051-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-051-19n      Applicant #: 2002-457XRAB  
Received: February 20, 2002      Effective: March 22, 2002  
Institution: Monsanto      Recipient: Wheat  
Interstate destination: MO ND  
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 03/05/02

State: MO

Rptloc01/R4

MAR 6 2002



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An Equal Opportunity Employer  
OR120018\_BR\_009473



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

*Release*

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

February 22, 2002

Dear Mr. Nelson:

Enclosed is notification 02-051-19n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-051-19n  
Received: February 20, 2002  
Institution: Monsanto  
Interstate destination: MO ND  
Release destination: ND

Applicant #: 2002-457XRAB  
Effective: March 22, 2002  
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination. *With attached condition*

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Signature (b) (6), (b) (7)(C)

Date: 3/18

State: ND

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_009474

March 21, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 22, 2002.

Interstate movement and Release  
Notification no. 02-051-19n (2002-457XRAB)  
Regulated article - Wheat  
Destinations - Missouri, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of North Dakota has (attached) modification of conditions for release of wheat.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

CC:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND  
File number 02-051-19n

OR120018\_BR\_009475

AGRICULTURE COMMISSIONER  
ROGER JOHNSON



PHONE (701) 328-2231  
(800) 242-7535  
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE  
State of North Dakota  
600 E. Boulevard Ave. Dept. 602  
Bismarck, ND 58505-0020

TO: Mary Jackson  
Biotechnology Program Operations – Permit Unit  
USDA APHIS  
4700 River Road  
Riverdale MD 207037  
**(b) (6), (b) (7)(C)**

FROM: David R. Nelson

DATE: March 27, 2002

RE: Modification of Conditions for Release of Wheat  
02-022-59n  
02-051-19n  
02-046-30n  
02-022-57n

Following further discussions with Monsanto we are making a slight modification in the conditions for release of the wheat notifications listed above.

**North Dakota Supplemental Conditions 2002**

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers:
  - Wheat should not be grown within the field trial area nor within 33 feet of the field trial area during the subsequent growing season and any wheat volunteers appearing within this area should be destroyed prior to flowering.
  - If wheat grown for harvest as grain is grown within 330 feet of the field trial during the year of the field trial, then wheat intended for use as seed should not be grown within this area during the following year.

cc: Danny Gigax, Monsanto

OR120018\_BR\_009476

AGRICULTURE COMMISSIONER  
ROGER JOHNSON



PHONE (701) 328-2231  
(800) 242-7535  
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE  
State of North Dakota  
600 E. Boulevard Ave. Dept. 602  
Bismarck, ND 58505-0020

TO: Mary Jackson  
USDA-APHIS-PPQ  
Permits-Biotechnology  
4700 River Road  
Riverdale MD 20737  
**(b) (6), (b) (7)(C)**

FROM: David R. Nelson [REDACTED]

DATE: February 28, 2002

RE: Bp number 02-051-19n

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.
3. Because of the possibility of volunteers, wheat should not be grown within the field trial or isolation area during the subsequent growing season and all volunteer wheat appearing within this area should be destroyed.

OR120018\_BR\_009477

MODE = MEMORY TRANSMISSION

START=APR-09 15:36 END=APR-09 15:49

FILE NO.=881

STN NO.	COMM.	ABBR NO.	STATION NAME/TEL NO.	PAGES	DURATION
001	OK	8	916367377085	005/005	00:05:33

\*\*\*\*\* - \*\*\*\* -



United States  
Department of  
Agriculture

Permits &  
Risk  
Assessments

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

March 21, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy N.  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

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7 CFR 340.3(c), effective on or after March 22, 2002.

Interstate movement and Release  
Notification no. 02-051-19n (2002-457XRAB)  
Regulated article - Wheat  
Destinations - Missouri, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of North Dakota has (attached) modification of conditions for release of wheat.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

CC:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND



APHIS- Protecting American Agriculture

Equal Opportunity Employer

OR120018\_BR\_009478

*CONFIDENTIAL*

**2002 Wheat Field Test Report**  
**USDA #02-051-19n**      **Monsanto #2002-457XRAB**

**September 19, 2003**

**Biotech Field Compliance Team**  
**Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
2147315762	Cass	ND
1611677957	Foster	ND
2147310478	Ward	ND
2147307343	Cavalier	ND

Cass County/ND (2147315762)

(b) (4)

(b) (4)

Cavalier County/ND (2147307343)

(b) (4)

(b) (4)

## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

**2002 Wheat Field Test Report**  
USDA #02-051-19n                    Monsanto #2002-457XRAB

**September 19, 2003**

## **Biotech Field Compliance Team Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
2147315762	Cass	ND	
1611677957	Foster	ND	Not Planted
2147310478	Ward	ND	Not Planted
2147307343	Cavalier	ND	

**Cass County/ND (2147315762)**

**Planting Date:** 05/22/2002

**Harvest Date:** 08/23/2002

**Destruct Date:** 08/23/2002

### **Vector Constructs/Line Numbers Planted: [CBI-Deleted]**

**Purpose of Field Trial:** [CBI-Deleted]

## **Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]**

## **Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]**

## **Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]**

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

## **Field Monitoring Observations for Plant Stand: [CBI-Deleted]**

**Disposition of the Harvested Material: [CBI-Deleted]**

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

Cavalier County/ND (2147307343)

**Planting Date:** 05/16/2002

**Destruct Date:** 09/13/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

MONSANTO



**CONFIDENTIAL**

MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

April 7, 2004

Mr. Juan A. Roman  
Team Leader  
Permitting and Notification  
USDA, APHIS  
4700 River Road, Unit 147  
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the farm (or company) name and/or address for the approved notifications:

<u>USDA#</u>	<u>Monsanto#</u>
02-022-57n	2002-256XRAB
02-051-19n	2002-457XRAB
03-015-10n	2003-22XRAB
03-052-27n	2003-205XRAB
04-021-05n	2004-36XRAB

The former name/address information is:

(b) (4)

The new name/address information is:

(b) (4)

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

Cc: Ralph Stoaks

OR120018\_BR\_009486

MONSANTO



**CBI - DELETED**

MONSANTO COMPANY  
700 CHESTERFIELD PKWY WEST  
CHESTERFIELD, MISSOURI 63017  
<http://www.monsanto.com>

April 7, 2004

Mr. Juan A. Roman  
Team Leader  
Permitting and Notification  
USDA, APHIS  
4700 River Road, Unit 147  
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the farm (or company) name and/or address for the approved notifications:

<u>USDA#</u>	<u>Monsanto#</u>
02-022-57n	2002-256XRAB
02-051-19n	2002-457XRAB
03-015-10n	2003-22XRAB
03-052-27n	2003-205XRAB
04-021-05n	2004-36XRAB

The former name/address information is:  
[CBI DELETED] - Cavalier, ND

The new name/address information is:  
[CBI DELETED] - Cavalier, ND

If you have any questions, please contact me at [REDACTED] (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)  
[REDACTED]

Cc: Ralph Stoaks

OR120018\_BR\_009487

=====
 Bp number: 02-051-25n  
 =====

App number: 2002-441XRAB                      Begin movement: 3/17/02  
 Received: 2/20/02                              End movement: 3/17/03  
 Institution: Monsanto                            Begin release: 3/17/02  
 Recipient: Wheat                                End release: 3/17/03  
 Status: Pending                                Acre: 3.00  
 Effective date: 3/22/02                        CBI status: CBI  
 Phenotype: HT - Glyphosate tolerant  
 Comments:  
 Resp person: [REDACTED] (b) (6), (b) (7)(C)  
 Parsed name:  
 Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway N.  
 Address3:  
 Address4:  
 City/State/Zip: Chesterfield, MO 63198  
 Telephone: (b) (6), (b) (7)(C)                      Fax: 636-737-7085

=====

- |  | Initial  | Date          |
|--|----------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ apd ]  | [ 2/25/02 ]   |
| 2. <input type="checkbox"/> Review by biotechnologist                          | [ Qv ] * | [ ] *         |
| 3. <input checked="" type="checkbox"/> Letter of notification to State FedEx   | [ KLnD ] | [ 2/27/02 ] * |
| 4. <input type="checkbox"/> State response                                     |          |               |

- | O/d Loc Site Reg   |          |              |  |
|--|----------|--------------|--|
| Interstate *Dest*ID * *WR *  | [ ]      | [ ]          |  |
| Interstate *Dest*MO * *SCR *   | [ ]      | [ ]          |  |
| Interstate *Orig*ID * *WR *  | [ ]      | [ ]          |  |
| Interstate *Orig*MO * *SCR *   | [ ]      | [ ]          |  |
| Release * *ID * 1*WR *   | [ ]      | [ ]          |  |
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ apd ]  | [ 2/25/02 ]  |  |
| 6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw   | [ KLnD ] | [ 3/7/02 ] * |  |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ KLnD ] | [ 3/8/02 ]   |  |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |          |              |  |



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-441XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-051-25n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-441XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 17, 2002 - March 17, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:**

HT

**Phenotype:**

Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite and elite lines

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-441XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVaI2 -- [REDACTED]

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [REDACTED]

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-441XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

100 pounds Ship up to \_100\_\_\_\_\_ pounds wheat seed to and from each location.

**ORIGIN:**

ID, MO

**DESTINATION:**

ID, MO

**Ship From:**

ID

\*[ (b) (4) Bingham County/Province,  
ID, (b) (4) USA ] - CBI

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

\*[ (b) (4) St. Louis County/Province, MO (b) (4) USA ] - CBI

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MO (b) (4), (b) (6), (b) (7)(C)

] - CBI

**Ship To:**

ID

\*[ (b) (4) Bingham County/Province,  
ID, (b) (4) USA ] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-441XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

\*[(b) (4)] St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO (b) (4), (b) (6), (b) (7)(C)

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-441XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (1)

ID

[REDACTED] (b) (4) [REDACTED] Bingham County/Province,  
ID, USA, 3 acres. [REDACTED] (b) (4) [REDACTED]

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

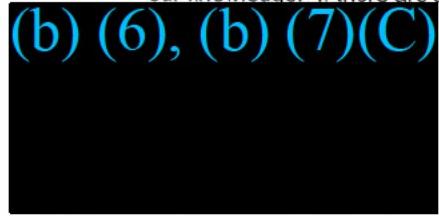
*CONFIDENTIAL*

Monsanto Reference ID  
2002-441XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

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For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costle, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organsim appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

CBI-DELETED

**Monsanto Reference ID**

2002-441XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-051-25n

**1. USDA Reference Number****2. Applicant Reference Number** 2002-441XRAB**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 636/737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 17, 2002 - March 17, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article****Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite and elite lines

# CBI-DELETED

**Monsanto Reference ID**

2002-441XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

# *CBI-DELETED*

**Monsanto Reference ID**

2002-441XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

100 pounds Ship up to \_100\_\_\_\_\_pounds wheat seed to and from each location.

**ORIGIN:**

ID, MO

**DESTINATION:**

ID, MO

**Ship From:**

ID

[ CBI Deleted ] -- \*Bingham County/Province, ID, USA

MO

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Ship To:**

ID

[ CBI Deleted ] -- \*Bingham County/Province, ID, USA

*CBI-DELETED*

Monsanto Reference ID  
2002-441XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-441XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ID (1)

**ID**

[  CBI Deleted ] -- Bingham County/Province, ID, USA, 3 acres

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

*CBI-DELETED*

Monsanto Reference ID

2002-441XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

*REDACTED*

**Monsanto Reference ID**

2002-441XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-051-25n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-441XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 636/737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 17, 2002 - March 17, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite and elite lines

**Monsanto Reference ID**

2002-441XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Monsanto Reference ID**

2002-441XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

100 pounds Ship up to 100 pounds wheat seed to and from each location.

**ORIGIN:**

ID, MO

**DESTINATION:**

ID, MO

**Ship From:**

ID

[ CBI Deleted ] -- \*Bingham County/Province, ID, USA

MO

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Ship To:**

ID

[ CBI Deleted ] -- \*Bingham County/Province, ID, USA

**Monsanto Reference ID**

2002-441XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Monsanto Reference ID**

2002-441XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ID (1)

**ID**

[ CBI Deleted ] -- Bingham County/Province, ID, USA, 3 acres

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

CELESTINE

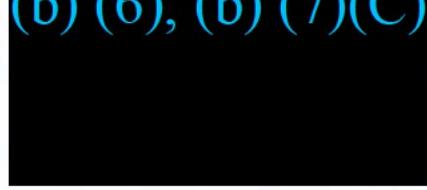
Monsanto Reference ID

2002-441XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

file copy

Dr. Rogelio R. Vega  
Division of Plant Industries  
Idaho Department of Agriculture  
2270 Old Penitentiary Road  
Boise, ID 83712

February 22, 2002

Dear Dr. Vega:

Enclosed is notification 02-051-25n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-051-25n	Applicant #:	2002-441XRAB
Received:	February 20, 2002	Effective:	March 22, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009510

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 22, 2002

Dear Mr. Brown:

Enclosed is notification 02-051-25n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-051-25n	Applicant #:	2002-441XRAB
Received:	February 20, 2002	Effective:	March 22, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009511



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Dr. Rogelio R. Vega  
Division of Plant Industries  
Idaho Department of Agriculture  
2270 Old Penitentiary Road  
Boise, ID 83712

February 22, 2002

**RECEIVED**  
**FEB 28 2002**  
**PLANT INDUSTRIES**

Dear Dr. Vega:

Enclosed is notification 02-051-25n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-051-25n	Applicant #:	2002-441XRAB
Received:	February 20, 2002	Effective:	March 22, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID MO		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Signature: (b) (6), (b) (7)(C)

Date: 2/28/02

State: IDAHO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

FEB 28 2002

OR120018\_BR\_009512



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

February 22, 2002

Dear Mr. Brown:

Enclosed is notification 02-051-25n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-051-25n      Applicant #: 2002-441XRAB  
Received: February 20, 2002      Effective: March 22, 2002  
Institution: Monsanto      Recipient: Wheat  
Interstate destination: ID MO  
Release destination: ID

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 03/05/02

State: MO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

MAR 6 2002

OR120018\_BR\_009513

March 7, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 17, 2002.

Interstate movement and Release  
Notification no. 02-051-25n (2002-441XRAB)  
Regulated article - Wheat  
Destinations - Idaho, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

cc:

R. Vega, Idaho Dept. of Agric., Boise, ID  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
File number 02-051-25n

OR120018\_BR\_009514

*No CBI*

**2002 Wheat Field Test Report**  
**USDA #02-051-25n**      **Monsanto #2002-441XRAB**

**September 19, 2003**

**Biotech Field Compliance Team**  
**Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
2147311778	Bingham	ID      Not Planted

=====
 Bp number: 02-060-05n  
 =====

App number: 2002-486XRAB                      Begin movement: 3/29/02  
 Received: 3/01/02                              End movement: 3/29/03  
 Institution: Monsanto                            Begin release: 3/29/02  
 Recipient: Wheat                                End release: 3/29/03  
 Status: Pending                                Acre: 10.00  
 Effective date: 3/31/02                        CBI status: CBI  
 Phenotype: HT - Glyphosate tolerant  
 Comments:  
 Resp person: [REDACTED] (b) (6), (b) (7)(C)  
 Parsed name:  
 Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway N.  
 Address3:  
 Address4:  
 City/State/Zip: Chesterfield, MO 63198  
 Telephone: (b) (6), (b) (7)(C)                      Fax: 636-737-7085  
 =====

- |  | Initial  | Date        |
|--|----------|-------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ apd ]  | [ 3/5/02 ]  |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist               | [ JT ]*  | [ 3/5/02 ]* |
| 3. <input type="checkbox"/> Letter of notification to State Fed-ex             | [ KLnD ] | [ 3/8/02 ]* |
| 4. <input type="checkbox"/> State response                                     |          |             |

O/d	Loc	Site	Reg				
Interstate	*Dest*CA	*	*WR	*	[ ]	[ ]	
Interstate	*Dest*ID	*	*WR	*	[ ]	[ ]	
Interstate	*Dest*KS	*	*SCR	*	[ ]	[ ]	
Interstate	*Dest*MO	*	*SCR	*	[ ]	[ ]	
Interstate	*Dest*WA	*	*WR	*	[ ]	[ ]	
Interstate	*Orig*CA	*	*WR	*	[ ]	[ ]	
Interstate	*Orig*ID	*	*WR	*	[ ]	[ ]	
Interstate	*Orig*KS	*	*SCR	*	[ ]	[ ]	
Interstate	*Orig*MO	*	*SCR	*	[ ]	[ ]	
Interstate	*Orig*WA	*	*WR	*	[ ]	[ ]	
Release	*	*ID	*	1*WR	*	[ ]	[ ]

- |  |          |              |
|--|----------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ apd ]  | [ 3/5/02 ]   |
| 6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw   | [ KLnD ] | [ 3/28/02 ]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ KLnD ] | [ 4/1/02 ]   |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |          |              |



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63108  
<http://www.monsanto.com>

CONFIDENTIAL

**Monsanto Reference ID**

2002-486XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-060-05n

**1. USDA Reference Number**

2. Applicant Reference Number 2002-486XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)  
FAX 636/737-7085  
EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 29, 2002 - March 29, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Oxen, Ingot, HJ-98, McNeal, BW-251, BW-252

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-486XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 --

(b) (4)  
(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

# CONFIDENTIAL

**Monsanto Reference ID**

2002-486XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

50000 Ship up to 50,000 pounds wheat seed to and from each location.

**ORIGIN:**

CA, ID, KS, MO, WA

**DESTINATION:**

CA, ID, KS, MO, WA

**Ship From:**

CA

(b) (4)

Imperial County/Province, CA (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

, CA (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

ID

(b) (4), (b) (6), (b) (7)(C) Lewis County/Province, ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

WA, (b) (4) USA,

] - CBI

KS

(b) (4)

Sedgwick County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-486XRAB

**MO**

\* [REDACTED] (b) (4) [REDACTED] St. Louis County/Province, MO (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] MO, [REDACTED]  
USA, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

**WA**

\* (b) (4), (b) (6), (b) (7)(C) Whitman County/Province, WA, [REDACTED] USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] WA [REDACTED] USA,  
[REDACTED]

] - CBI

**Ship To:**

**CA**

\* [REDACTED] (b) (4) [REDACTED] Imperial County/Province, CA (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] CA [REDACTED] USA,  
[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

**ID**

\* (b) (4), (b) (6), (b) (7)(C) Lewis County/Province, ID [REDACTED] USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] WA [REDACTED] USA,  
[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**  
2002-486XRAB

**KS**

\*[ (b) (4) ] - Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

**MO**

\*[ (b) (4) ] - St. Louis County/Province, MO, (b) (4) USA

CONTACT: USA, (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)

] - CBI

**WA**

\*[ (b) (4), (b) (6), (b) (7)(C) ] - Whitman County/Province, WA, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-486XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ID (1)

**ID**

(b) (4), (b) (6), (b) (7)(C) Lewis County/Province, ID, USA, 10 acres. (b) (4), (b) (6), (b) (7)(C)

[REDACTED] RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
[REDACTED] WA, [REDACTED] USA, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-486XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982)..

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

#### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

*CBI-DELETED***Monsanto Reference ID**

2002-486XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-060-05n

**1. USDA Reference Number**

2. Applicant Reference Number 2002-486XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 29, 2002 - March 29, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article****Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Oxen, Ingot, HJ-98, McNeal, BW-251, BW-252

# *CBI-DELETED*

**Monsanto Reference ID**

2002-486XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

# *CBI-DELETED*

**Monsanto Reference ID**

2002-486XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

50000 Ship up to 50,000 pounds wheat seed to and from each location.

**ORIGIN:**

CA, ID, KS, MO, WA

**DESTINATION:**

CA, ID, KS, MO, WA

**Ship From:****CA**[  CBI Deleted ] -- \*Imperial County/Province, CA, USA**ID**[  CBI Deleted ] -- \*Lewis County/Province, ID, USA**KS**[  CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-486XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**WA**

[ CBI Deleted ] -- \*Whitman County/Province, WA, USA

**Ship To:**

**CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

**ID**

[ CBI Deleted ] -- \*Lewis County/Province, ID, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-486XRAB

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**WA**

[ CBI Deleted ] -- \*Whitman County/Province, WA, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-486XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ID (1)

**ID**

[ CBI Deleted ] -- Lewis County/Province, ID, USA, 10 acres

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63108  
<http://www.monsanto.com>

*CBI-DELETED*

**Monsanto Reference ID**

2002-486XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-486XRB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-060-05n

- 1. USDA Reference Number**
- 2. Applicant Reference Number** 2002-486XRB
- 3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 636/737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis MO 63198

**4. Duration of Introduction**

Interstate Movement and Release

March 29, 2002 - March 29, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Oxen, Ingot, HJ-98, McNeal, BW-251, BW-252

**Monsanto Reference ID**

2002-486XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [  CBI Deleted  ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [  CBI Deleted  ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Monsanto Reference ID**

2002-486XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

50000 Ship up to 50,000 pounds wheat seed to and from each location.

**ORIGIN:**

CA, ID, KS, MO, WA

**DESTINATION:**

CA, ID, KS, MO, WA

**Ship From:**

**CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

**ID**

[ CBI Deleted ] -- \*Lewis County/Province, ID, USA

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**Monsanto Reference ID**

2002-486XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**WA**

[ CBI Deleted ] -- \*Whitman County/Province, WA, USA

**Ship To:**

**CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

**ID**

[ CBI Deleted ] -- \*Lewis County/Province, ID, USA

**Monsanto Reference ID**

2002-486XRAB

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**WA**

[ CBI Deleted ] -- \*Whitman County/Province, WA, USA

**Monsanto Reference ID**

2002-486XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

ID (1)

**ID**

[ CBI Deleted ] -- Lewis County/Province, ID, USA, 10 acres

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

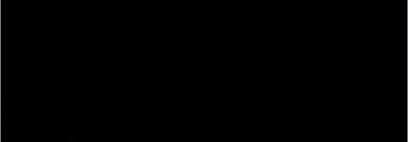
Monsanto Reference ID

2002-486XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

file copy

Ms. Barbara Hass, State Regulatory Official  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

March 5, 2002

Dear Ms. Hass:

Enclosed is notification 02-060-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-060-05n                      Applicant #: 2002-486XRAB  
Received: March 1, 2002                      Effective: March 31, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: CA ID KS MO WA  
Release destination: ID

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009541

file copy

Dr. Rogelio R. Vega  
Division of Plant Industries  
Idaho Department of Agriculture  
2270 Old Penitentiary Road  
Boise, ID 83712

March 5, 2002

Dear Dr. Vega:

Enclosed is notification 02-060-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-060-05n	Applicant #:	2002-486XRAB
Received:	March 1, 2002	Effective:	March 31, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: CA ID KS MO WA			
Release destination: ID			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009542

file copy

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

March 5, 2002

Dear Mr. Sim IV:

Enclosed is notification 02-060-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-060-05n                      Applicant #: 2002-486XRAB  
Received: March 1, 2002                      Effective: March 31, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: CA ID KS MO WA  
Release destination: ID

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[S]

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009543

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

March 5, 2002

Dear Mr. Brown:

Enclosed is notification 02-060-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-060-05n	Applicant #:	2002-486XRAB
Received:	March 1, 2002	Effective:	March 31, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: CA ID KS MO WA			
Release destination: ID			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,



Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009544

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

March 5, 2002

Dear Mr. Wessels:

Enclosed is notification 02-060-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-060-05n	Applicant #:	2002-486XRAB
Received:	March 1, 2002	Effective:	March 31, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA ID KS MO WA		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(S)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009545



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Ms. Barbara Hass, State Regulatory Official  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

March 5, 2002

Dear Ms. Hass:

Enclosed is notification 02-060-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-060-05n                      Applicant #: 2002-486XRA  
Received: March 1, 2002                      Effective: March 31, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: CA ID KS MO WA  
Release destination: ID

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Barbara J Hass

Signature: (b) (6), (b) (7)(C)

Date: March 13, 2002

State: California

Rptloc01/R4



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An Equal Opportunity Employer

MAR 14 2002

OR120018\_BR\_009546



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Dr. Rogelio R. Vega  
Division of Plant Industries  
Idaho Department of Agriculture  
2270 Old Penitentiary Road  
Boise, ID 83712

**RECEIVED**

March 5, 2002

MAR 11 2002

**PLANT INDUSTRIES**

Dear Dr. Vega:

Enclosed is notification 02-060-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-060-05n

Applicant #: 2002-486XRB

Received: March 1, 2002

Effective: March 31, 2002

Institution: Monsanto

Recipient: Wheat

Interstate destination: CA ID KS MO WA

Release destination: ID

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Signature: (b) (6), (b) (7)(C)

Date: 3/11/02

State: IDAHO

Rptloc01/R4



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MAR 11 2002



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

March 5, 2002

Dear Mr. Sim IV:

Enclosed is notification 02-060-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-060-05n                      Applicant #: 2002-486XRAB  
Received: March 1, 2002                      Effective: March 31, 2002  
Institution: Monsanto                          Recipient: Wheat  
Interstate destination: CA ID KS MO WA  
Release destination: ID

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



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OR120018\_BR\_009548



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

March 5, 2002

Dear Mr. Brown:

Enclosed is notification 02-060-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-060-05n                      Applicant #: 2002-486XRB  
Received: March 1, 2002                      Effective: March 31, 2002  
Institution: Monsanto                          Recipient: Wheat  
Interstate destination: CA ID KS MO WA  
Release destination: ID

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

*Michael E. Brown*

Signature: (b) (6), (b) (7)(C)

Date: 03/11/02

State: MO

Rptloc01/R4



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5737510005 P.17/20

An Equal Opportunity Employer

OR120018\_BR\_009549

DEPT OF AGRICULTURE

MAR-12-2002 07:53

MAR 12 2002



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

March 5, 2002

Dear Mr. Wessels:

Enclosed is notification 02-060-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-060-05n	Applicant #:	2002-486XRB
Received:	March 1, 2002	Effective:	March 31, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: CA ID KS MO WA			
Release destination: ID			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

✓ State concurs with APHIS determination.

       State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 3/11/02

State: WA

Rptloc01/R4



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MAR 11 2002

OR120018\_BR\_009550

March 28, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 31, 2002.

**Interstate movement and Release**

Notification no. 02-060-05n (2002-486XRAB)

Regulated article - Wheat

Destinations - California, Idaho, Kansas, Missouri, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

cc:

B. Hass, California Dept. of Food and Agric., Sacramento, CA  
R. Vega, Idaho Dept. of Agric., Boise, ID  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
T. Wessels, Washington Dept. of Agric., Olympia, WA  
File number 02-060-05n

*No CBI*

**2002 Wheat Field Test Report**  
**USDA #02-060-05n**      **Monsanto #2002-486XRAB**

**September 19, 2003**

**Biotech Field Compliance Team**  
**Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
2147315822	Lewis	ID      Not Planted

=====
 Bp number: 02-060-06n  
 =====

App number: 2002-487XRAB      Begin movement: 3/29/02  
 Received: 3/01/02      End movement: 3/29/03  
 Institution: Monsanto      Begin release: 3/29/02  
 Recipient: Wheat      End release: 3/29/03  
 Status: Pending      Acre: 10.00  
 Effective date: 3/31/02      CBI status: CBI  
 Phenotype: HT - Glyphosate tolerant

Comments:

Resp person:  
Parsed name:

(b) (6), (b) (7)(C)

Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield, MO 63198

Telephone: (b) (6), (b) (7)(C)

Fax:

636-737-7085

- |  | Initial | Date        |
|--|---------|-------------|
| 1. [✓] Assign Bp number and initial data entry | [ apd ] | [ 3/5/02 ]  |
| 2. [ ] Review by biotechnologist               | [ ]*    | [ 3/5/02 ]* |
| 3. [ ] Letter of notification to State Fed-ex  | [ KLN ] | [ 3/8/02 ]* |
| 4. [ ] State response                          |         |             |

O/d	Loc	Site	Reg				
Interstate	*Dest*CA	*	*WR	*	[ ]	[ ]	
Interstate	*Dest*CO	*	*WR	*	[ ]	[ ]	
Interstate	*Dest*KS	*	*SCR	*	[ ]	[ ]	
Interstate	*Dest*MO	*	*SCR	*	[ ]	[ ]	
Interstate	*Orig*CA	*	*WR	*	[ ]	[ ]	
Interstate	*Orig*CO	*	*WR	*	[ ]	[ ]	
Interstate	*Orig*KS	*	*SCR	*	[ ]	[ ]	
Interstate	*Orig*MO	*	*SCR	*	[ ]	[ ]	
Release	*	*CO	*	1*WR	*	[ ]	[ ]

- |   |         |              |
|---|---------|--------------|
| 5. [ ] Enter genes into database  | [ apd ] | [ 3/5/02 ]   |
| 6. [✓] Letter of acknowledgement/denial/withdraw  | [ KEP ] | [ 3/28/02 ]* |
| 7. [✓] Enter final data into database   | [ KLN ] | [ 4/1/02 ]   |
| 8. [ ] If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |         |              |



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

CONFIDENTIAL

**Monsanto Reference ID**

2002-487XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-060-06n

**1. USDA Reference Number**

2. Applicant Reference Number 2002-487XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)  
FAX 636/737-7085  
EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

March 29, 2002 - March 29, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Oxen, Ingot, HJ-98, McNeal, BW-251, BW-252

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-487XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [REDACTED]

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [REDACTED]

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-487XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

50,000 Ship up to 50,000 pounds wheat seed to and from each location.

**ORIGIN:**

CA, CO, KS, MO

**DESTINATION:**

CA, CO, KS, MO

**Ship From:**

CA

\* [REDACTED] (b) (4) Imperial County/Province, CA (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) CA [REDACTED] (b) (4) USA,  
[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

CO

\* [REDACTED] (b) (4) Rio Grande County/Province, CO (b) (4)

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED], CO [REDACTED] (b) (4) USA,  
[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

KS

\* [REDACTED] (b) (4) Sedgwick County/Province, KS (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) KS, [REDACTED] (b) (4) USA,  
[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**  
2002-487XRAB

**MO**

\*[ (b) (4) ] - CBI St. Louis County/Province, MO (b) (4) USA

CONTACT USA (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) St. Louis, MO (b) (4)

] - CBI

**Ship To:**

**CA**

\*[ (b) (4) ] - CBI Imperial County/Province, CA (b) (4) USA

CONTACT USA (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) CA, (b) (4) USA,

] - CBI

**CO**

\*[ (b) (4) ] - CBI Rio Grande County/Province, CO (b) (4)

CONTACT USA (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) CO (b) (4)

] - CBI

**KS**

\*[ (b) (4) ] - CBI Sedgwick County/Province, KS (b) (4) USA

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-487XRAB

CONTACT: [REDACTED]  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

KS, [REDACTED] USA,

] - CBI

MO

\* [REDACTED] (b) (4) St. Louis County/Province, MO (b) (4) USA

CONTACT: [REDACTED]  
USA, [REDACTED]

(b) (4), (b) (6), (b) (7)(C)

MO [REDACTED]

] - CBI

*CONFIDENTIAL*

**Monsanto Reference ID**

2002-487XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

CO (1)

CO

[REDACTED] (b) (4) Rio Grande County/Province, CO, USA, 10  
acres. (b) (4) [REDACTED]

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



*CONFIDENTIAL*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

Monsanto Reference ID

2002-487XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C. Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C. Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982)..

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costle, 622 F.2d 45, 51-52 (D.C. Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

#### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organsim appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63108  
<http://www.monsanto.com>*CBI-DELETED***Monsanto Reference ID**

2002-487XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-060-06n

**1. USDA Reference Number****2. Applicant Reference Number** 2002-487XRAB**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

monsanto.com

**4. Duration of Introduction**

Interstate Movement and Release

March 29, 2002 - March 29, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article****Phenotypic Category:** HT**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Oxen, Ingot, HJ-98, McNeal, BW-251, BW-252

# *CBI-DELETED*

**Monsanto Reference ID**

2002-487XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

*CBI-DELETED*

**Monsanto Reference ID**

2002-487XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

50,000 Ship up to 50,000 pounds wheat seed to and from each location.

**ORIGIN:**

CA, CO, KS, MO

**DESTINATION:**

CA, CO, KS, MO

**Ship From:**

**CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

**CO**

[ CBI Deleted ] -- \*Rio Grande County/Province, CO, USA

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-487XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Ship To:**

**CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

**CO**

[ CBI Deleted ] -- \*Rio Grande County/Province, CO, USA

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

*CBI-DELETED*

**Monsanto Reference ID**  
2002-487XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-487XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CO (1)

**CO**

[ CBI Deleted ] -- Rio Grande County/Province, CO, USA, 10 acres

MONSANTO



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

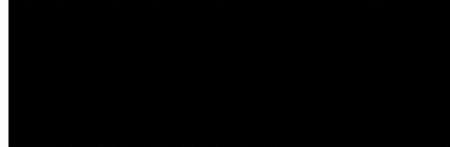
Monsanto Reference ID

2002-487XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-487XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-060-06n

- 1. USDA Reference Number**
- 2. Applicant Reference Number** 2002-487XRAB
- 3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 636/737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis MO 63198

**4. Duration of Introduction**

Interstate Movement and Release

March 29, 2002 - March 29, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Oxen, Ingot, HJ-98, McNeal, BW-251, BW-252

**Monsanto Reference ID**

2002-487XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Monsanto Reference ID**

2002-487XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

50,000 Ship up to 50,000 pounds wheat seed to and from each location.

**ORIGIN:**

CA, CO, KS, MO

**DESTINATION:**

CA, CO, KS, MO

**Ship From:**

**CA**

[  CBI Deleted ] -- \*Imperial County/Province, CA, USA

**CO**

[  CBI Deleted ] -- \*Rio Grande County/Province, CO, USA

**KS**

[  CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**Monsanto Reference ID**  
2002-487XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Ship To:**

**CA**

[ CBI Deleted ] -- \*Imperial County/Province, CA, USA

**CO**

[ CBI Deleted ] -- \*Rio Grande County/Province, CO, USA

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**Monsanto Reference ID**  
2002-487XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Monsanto Reference ID**

2002-487XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CO (1)

**CO**

[ CBI Deleted ] -- Rio Grande County/Province, CO, USA, 10 acres

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

Monsanto Reference ID

2002-487XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

file copy

Ms. Barbara Hass, State Regulatory Official  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

March 5, 2002

Dear Ms. Hass:

Enclosed is notification 02-060-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-060-06n                      Applicant #: 2002-487XRAB  
Received: March 1, 2002                      Effective: March 31, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: CA CO KS MO  
Release destination: CO

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009578

file copy

Mr. Mitch Yergert  
Colorado Department of Agriculture  
700 Kipling Street - Suite 4000  
Lakewood, CO 80215-5894

March 5, 2002

Dear Mr. Yergert:

Enclosed is notification 02-060-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-060-06n                      Applicant #: 2002-487XRAB  
Received: March 1, 2002                      Effective: March 31, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: CA CO KS MO  
Release destination: CO

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009579



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

March 5, 2002

Dear Mr. Sim IV:

Enclosed is notification 02-060-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-060-06n                      Applicant #: 2002-487XRAB  
Received: March 1, 2002                      Effective: March 31, 2002  
Institution: Monsanto                          Recipient: Wheat  
Interstate destination: CA CO KS MO  
Release destination: CO

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



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An Equal Opportunity Employer

OR120018\_BR\_009580

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

March 5, 2002

Dear Mr. Brown:

Enclosed is notification 02-060-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-060-06n                      Applicant #: 2002-487XRAB  
Received: March 1, 2002                      Effective: March 31, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: CA CO KS MO  
Release destination: CO

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009581



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Ms. Barbara Hass, State Regulatory Official  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

March 5, 2002

Dear Ms. Hass:

Enclosed is notification 02-060-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-060-06n	Applicant #:	2002-487XRAB
Received:	March 1, 2002	Effective:	March 31, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: CA CO KS MO			
Release destination:		CO	

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely  
**(b) (6), (b) (7)(C)**

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Barbara J Hass

Signature: **(b) (6), (b) (7)(C)**

Date: March 13, 2002

State: California

Rptloc01/R4



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An Equal Opportunity Employer

MAR 14 2002

OR120018\_BR\_009582



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Mitch Yergert  
Colorado Department of Agriculture  
700 Kipling Street - Suite 4000  
Lakewood, CO 80215-5894

March 5, 2002

Dear Mr. Yergert:

Enclosed is notification 02-060-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-060-06n                      Applicant #: 2002-487XRAB  
Received: March 1, 2002                      Effective: March 31, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: CA CO KS MO  
Release destination: CO

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

sincerely

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: MITCHELL YERGERT

Signature: (b) (6), (b) (7)(C)

Date: MARCH 12, 2002

State: COLORADO

Rptloc01/R4



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An Equal Opportunity Employer

MAR 12 2002

OR120018\_BR\_009583



Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

March 5, 2002

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

Dear Mr. Brown:

Enclosed is notification 02-060-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-060-06n	Applicant #:	2002-487XRAB
Received:	March 1, 2002	Effective:	March 31, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: CA CO KS MO			
Release destination: CO			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of state official: (b) (6), (b) (7)(C)

Signature: MICHAEL E. BROWN

Date: 03/11/02

State: MD

Rptloc01/R4



APHIS - Protecting American Agriculture

5737510005 P.20/20

OR120018\_BR\_009584

DEPT OF AGRICULTURE

MAR-12-2002 07:56

MAR 12 2002

March 28, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C),

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 31, 2002.

Interstate movement and Release  
Notification no. 02-060-06n (2002-487XRAB)  
Regulated article - Wheat  
Destinations - California, Colorado, Kansas, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

cc:

B. Hass, California Dept. of Food and Agric., Sacramento, CA  
M. Yergert, Colorado Dept. of Agric., Lakewood, CO  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
File number 02-060-06n

*CONFIDENTIAL*

**2002 Wheat Field Test Report**  
**USDA #02-060-06n**      **Monsanto #2002-487XRAB**

**September 19, 2003**

**Biotech Field Compliance Team**  
**Monsanto Company**

**Location**

2147318081

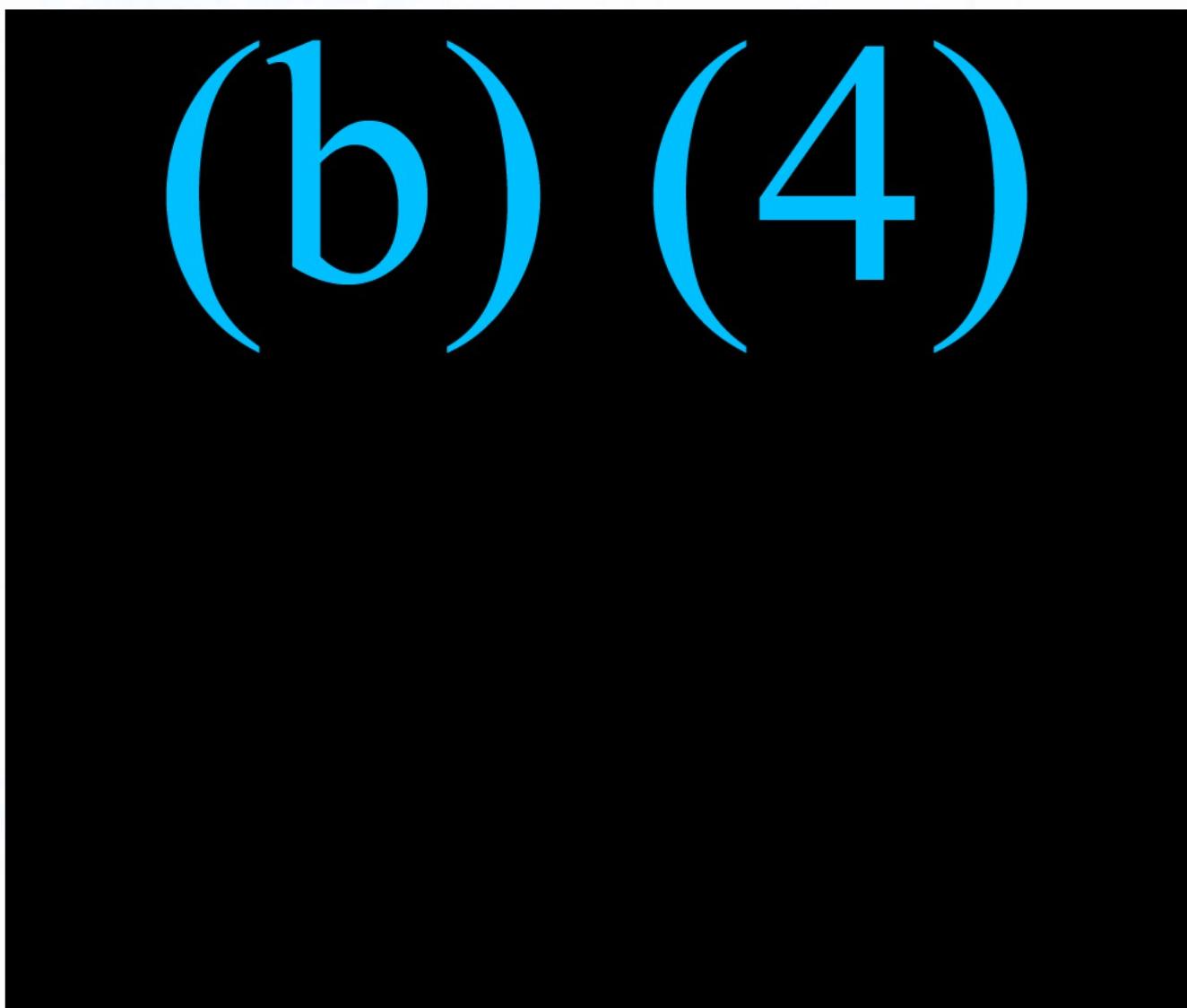
**County**

Rio Grande

**State**

CO

Rio Grande County/CO (2147318081)



(b) (4)

## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

*CBI-DELETED*

**2002 Wheat Field Test Report  
USDA #02-060-06n                    Monsanto #2002-487XRAB**

**September 19, 2003**

**Biotech Field Compliance Team  
Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
2147318081	Rio Grande	CO

**Rio Grande County/CO (2147318081)**

**Planting Date:** 05/24/2002

**Harvest Date:** 10/08/2002

**Destruct Date:** 10/14/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

CONTAINS CBI

April 22, 2002

Ms. Mary Jackson  
Animal and Plant Health Inspection Services  
Biotechnology and Scientific Services  
4700 River Road, Unit 147  
Riverdale, MD

Dear Ms. Jackson;

In reviewing Monsanto's acknowledged wheat notification it was discovered an error was given in the release information. The Monsanto number is 2002-487XRAB, USDA # 02-060-06n. The notification lists the release site as [REDACTED] (b) (4)  
CO, responsible researcher (b) (4), (b) (6), (b) (7)(C) It should read (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) [REDACTED] CO, responsible researcher  
(b) (4), (b) (6), (b) (7)(C) [REDACTED]  
(b) (4), (b) (6), (b) (7)(C) CO (b) (4), (b) (6), (b) (7)(C)

If you have any questions please call at (b) (6), (b) (7)(C)

Sincerely,  
(b) (6), (b) (7)(C)

Cc R. Stoaks, USDA APHIS, PPQ, Fort Collins, CO  
M. Yergert, Colorado Department of Agriculture, Lakewood, CO

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**C B I DELETED**

April 22, 2002

Ms. Mary Jackson  
Animal and Plant Health Inspection Services  
Biotechnology and Scientific Services  
4700 River Road, Unit 147  
Riverdale, MD

Dear Ms. Jackson;

In reviewing Monsanto's acknowledged wheat notification it was discovered an error was given in the release information. The Monsanto number is 2002-487XRAB, USDA # 02-060-06n. The notification lists the release site as [CBI deleted] . It should read [CBI deleted]

If you have any questions please call at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

Cc R. Stoaks, USDA APHIS, PPQ, Fort Collins, CO  
M. Yergert, Colorado Department of Agriculture, Lakewood, CO

=====  
 Bp number: 02-077-09n  
 =====

App number: 2002-494XRAB  
 Received: 3/18/02  
 Institution: Monsanto  
 Recipient: Wheat  
 Status: Pending  
 Effective date: 4/17/02  
 Phenotype: HT - Glyphosate tolerant  
 Comments:  
 Resp person: [REDACTED] (b) (6), (b) (7)(C)  
 Parsed name:  
 Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway N.  
 Address3:  
 Address4:  
 City/State/Zip: Chesterfield, MO 63198  
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085  
 =====

- |  | Initial | Date       |
|--|---------|------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [copy]  | [3/20/02]  |
| 2. <input type="checkbox"/> Review by biotechnologist                          | [DW]    | [ ]*       |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex  | [KLO]   | [3/22/02]* |
| 4. <input type="checkbox"/> State response                                     |         |            |

O/d	Loc	Site	Reg				
Interstate	*Dest*CO	*	*WR	*	[ ]	[ ]	
Interstate	*Dest*KS	*	*SCR	*	[ ]	[ ]	
Interstate	*Dest*MN	*	*NER	*	[ ]	[ ]	
Interstate	*Dest*MO	*	*SCR	*	[ ]	[ ]	
Interstate	*Orig*CO	*	*WR	*	[ ]	[ ]	
Interstate	*Orig*KS	*	*SCR	*	[ ]	[ ]	
Interstate	*Orig*MN	*	*NER	*	[ ]	[ ]	
Interstate	*Orig*MO	*	*SCR	*	[ ]	[ ]	
Release	*	*MN	*	1*NER	*	[ ]	[ ]

- |  |        |            |
|--|--------|------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [copy] | [3/30/02]  |
| 6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw   | [KLO]  | [4/17/02]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [KLO]  | [4/18/02]  |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |        |            |



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

CONFIDENTIAL

**Monsanto Reference ID**

2002-494XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-077-09n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-494XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

April 13, 2002 - April 13, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-494XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [REDACTED]

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [REDACTED]

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

*CONFIDENTIAL*

**Monsanto Reference ID**

2002-494XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

200 pounds Ship up to \_\_100\_\_pounds wheat seed to and from each location.

**ORIGIN:**

CO, KS, MN, MO

**DESTINATION:**

CO, KS, MN, MO

**Ship From:**

CO

\* [REDACTED] (b) (4) Weld County/Province, CO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

KS

\* [REDACTED] (b) (4) Geary County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

MN

\* [REDACTED] (b) (4) Polk County/Province, MN (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**  
2002-494XRAB

MO

\*[ (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: USA (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MO, (b) (4)

] - CBI

**Ship To:**

CO

\*[ (b) (4) Weld County/Province, CO, (b) (4) USA

CONTACT: USA (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

KS

\*[ (b) (4) Geary County/Province, KS (b) (4) USA

CONTACT: USA (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

MN

\*[ (b) (4) Polk County/Province, MN (b) (4) USA

*CONFIDENTIAL*

**Monsanto Reference ID**  
2002-494XRAB

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] CO, [REDACTED] USA,  
[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

\* [REDACTED] (b) (4) St. Louis County/Province, MO (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] MO, [REDACTED]  
USA, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

*CONFIDENTIAL*

**Monsanto Reference ID**

2002-494XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MN (1)

MN

(b) (4)

Polk County/Province, MN, USA, 4 acres.

(b) (4)

(b) (4), (b) (6), (b) (7)(C)  
RESPONSIBLE PERSON/RESEARCHER:  
CO (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

CONFIDENTIAL

Monsanto Reference ID

2002-494XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C. Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C. Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).-

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costle, 622 F.2d 45, 51-52 (D.C. Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

#### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organsim appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



CBI-DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-494XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-077-09n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-494XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 636/737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

April 13, 2002 - April 13, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

# CBI-DELETED

**Monsanto Reference ID**

2002-494XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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# *CBI-DELETED*

**Monsanto Reference ID**

2002-494XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

200 pounds Ship up to \_\_100\_\_pounds wheat seed to and from each location.

**ORIGIN:**

CO, KS, MN, MO

**DESTINATION:**

CO, KS, MN, MO

**Ship From:****CO**

[ CBI Deleted ] -- \*Weld County/Province, CO, USA

**KS**

[ CBI Deleted ] -- \*Geary County/Province, KS, USA

**MN**

[ CBI Deleted ] -- \*Polk County/Province, MN, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-494XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Ship To:**

**CO**

[ CBI Deleted ] -- \*Weld County/Province, CO, USA

**KS**

[ CBI Deleted ] -- \*Geary County/Province, KS, USA

**MN**

[ CBI Deleted ] -- \*Polk County/Province, MN, USA

*CBI-DELETED*

**Monsanto Reference ID**  
2002-494XRAB

**MO**

[  CBI Deleted ] -- \*St. Louis County/Province, MO, USA

*CBI-DELETED*

**Monsanto Reference ID**

2002-494XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MN (1)

**MN**

[ CBI Deleted ] -- Polk County/Province, MN, USA, 4 acres

MONSANTO



*CBI-DELETED*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-494XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-494XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-077-09n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-494XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis MO 63198

**4. Duration of Introduction**

Interstate Movement and Release

April 13, 2002 - April 13, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:**

HT

**Phenotype:**

Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

**Monsanto Reference ID**

2002-494XRAB

designation of transformed line:

33391

Constructs: PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Monsanto Reference ID**

2002-494XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

200 pounds Ship up to \_\_100\_\_pounds wheat seed to and from each location.

**ORIGIN:**

CO, KS, MN, MO

**DESTINATION:**

CO, KS, MN, MO

**Ship From:**

CO

[ CBI Deleted ] -- \*Weld County/Province, CO, USA

KS

[ CBI Deleted ] -- \*Geary County/Province, KS, USA

MN

[ CBI Deleted ] -- \*Polk County/Province, MN, USA

**Monsanto Reference ID**

2002-494XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Ship To:**

**CO**

[ CBI Deleted ] -- \*Weld County/Province, CO, USA

**KS**

[ CBI Deleted ] -- \*Geary County/Province, KS, USA

**MN**

[ CBI Deleted ] -- \*Polk County/Province, MN, USA

**Monsanto Reference ID**  
2002-494XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Monsanto Reference ID**

2002-494XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MN (1)

**MN**

[ CBI Deleted ] -- Polk County/Province, MN, USA, 4 acres

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

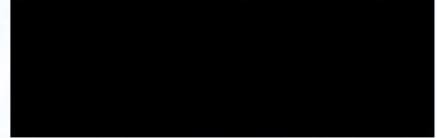
**Monsanto Reference ID**

2002-494XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

file copy

Mr. Mitch Yergert  
Colorado Department of Agriculture  
700 Kipling Street - Suite 4000  
Lakewood, CO 80215-5894

March 20, 2002

Dear Mr. Yergert:

Enclosed is notification 02-077-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-077-09n                      Applicant #: 2002-494XRAB  
Received: March 18, 2002                      Effective: April 17, 2002  
Institution: Monsanto                            Recipient: Wheat  
Interstate destination: CO KS MN MO  
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[S]

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009618

file copy

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

March 20, 2002

Dear Mr. Sim IV:

Enclosed is notification 02-077-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-077-09n	Applicant #:	2002-494XRAB
Received:	March 18, 2002	Effective:	April 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO KS MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009619

file copy

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

March 20, 2002

Dear Dr. Hanks:

Enclosed is notification 02-077-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-077-09n                      Applicant #: 2002-494XRAB  
Received: March 18, 2002                      Effective: April 17, 2002  
Institution: Monsanto                            Recipient: Wheat  
Interstate destination: CO KS MN MO  
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009620

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

March 20, 2002

Dear Mr. Brown:

Enclosed is notification 02-077-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-077-09n	Applicant #:	2002-494XRAB
Received:	March 18, 2002	Effective:	April 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO KS MN MO		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[S]

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009621



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Mitch Yergert  
Colorado Department of Agriculture  
700 Kipling Street - Suite 4000  
Lakewood, CO 80215-5894

March 20, 2002

Dear Mr. Yergert:

Enclosed is notification 02-077-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-077-09n                      Applicant #: 2002-494XRAB  
Received: March 18, 2002                      Effective: April 17, 2002  
Institution: Monsanto                            Recipient: Wheat  
Interstate destination: CO KS MN MO  
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

---

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: MITCHELL YERGERT

Signature:

(b) (6), (b) (7)(C)

Date: MARCH 27, 2002

State: COLORADO

Rptloc01/R4



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MAR 27 2002

OR120018\_BR\_009622



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Dr. Mary J. Hanks, Biotechnologist  
Plant Industry Division  
Minnesota Department of Agriculture  
90 West Plato Boulevard  
St. Paul, MN 55107

March 20, 2002

Dear Dr. Hanks:

Enclosed is notification 02-077-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-077-09n                      Applicant #: 2002-494XRAB  
Received: March 18, 2002                      Effective: April 17, 2002  
Institution: Monsanto                              Recipient: Wheat  
Interstate destination: CO KS MN MO  
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. *with the attached additional conditions*

State DOES NOT CONCUR and offers the following reasons:  
Name of State official: *Mary J. Hanks*

Signature: (b) (6), (b) (7)(C)

Date: *4-9-02*

State: *MN*

Rptloc01/R4





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

March 20, 2002

Dear Mr. Brown:

Enclosed is notification 02-077-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-077-09n	Applicant #:	2002-494XRAB
Received:	March 18, 2002	Effective:	April 17, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: CO KS MN MO			
Release destination: MN			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

[Redacted]  
Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 3/25/02

State: MO

Rptloc01/R4



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An Equal Opportunity Employer

MAR 26 2002

OR120018\_BR\_009624

April 17, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway N.  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 17, 2002.

Interstate movement and Release  
Notification no. 02-077-09n (2002-494XRAB)  
Regulated article - Wheat  
Destinations - Colorado, Kansas, Minnesota, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Minnesota has (attached) additional conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

[Signature]

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

cc:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
File number 02-077-09n



## Minnesota Department of Agriculture

(651) 296-1277

April 9, 2002

Ms. Mary Jackson  
Biotechnology Program Operations  
Permit Unit  
USDA APHIS  
4700 River Road  
Riverdale, MD 27037

RE: Additional Conditions for Release of Wheat 02-077-09n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (whcat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified seed as well as any grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain entering commercial grain markets must be at least 100 feet.
3. Because of the possibility of volunteers:
  - Wheat should not be grown within the field trial area nor within 10 feet of the field trial area during the subsequent growing season and any wheat volunteers appearing within this area should be destroyed prior to flowering.
  - If wheat grown for harvest as grain is grown within 330 feet of the field trial during the year of the field trial, then whcat intended for use as seed should not be grown within this area during the following year.

These conditions are in addition to those contained in the applicants "Wheat Field Release Performance Standards" as revised January 2002.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Hanks, Ph.D.  
State Biotechnologist



**USDA** United States  
Department of  
Agriculture

**Animal and  
Plant Health  
Inspection Service**

## Permits & Risk Assessments

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

April 17, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway N.  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to  
7 CFR 340.3(c), effective on or after April 17, 2002.

Interstate movement and Release  
Notification no. 02-077-09n (2002-494XR)  
Regulated article - Wheat  
Destinations - Colorado, Kansas, Minnesota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Minnesota has (attached) additional conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

**Enclosure**

cc:  
M. Yergert, Colorado Dept. of Agric., Lakewood, CO  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO



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An Equal Opportunity Employer

- \* \* \* \* -

FILE NO.=076  
MODE = MEMORY TRANSMISSION  
START-HR-18 11:50 END-HR-18 11:54  
STATION NAME/TEL NO. ABBR NO. COMM. STN NO.  
916367377085 002/002 00:03:42  
OK 001

09120018-BR-009627 \*CORPORAL-JOURNALISTIC-REPORTER-EDITORIALIST-OPINIONIST-ARTIST-COMM.

*No CBI*

**2002 Wheat Field Test Report**  
**USDA #02-077-09n**      **Monsanto #2002-494XRAB**

**October 16, 2003**

**Biotech Field Compliance Team**  
**Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
2147315828	Polk	MN      Not Planted

*ad*  
*10/17/03*

4/08/02 11:12 am

## Notification Tracking Sheet

=====
 Bp number: 02-093-07n  
 =====

App number: 2002-562XRAB      Begin movement: 4/26/02  
 Received: 4/03/02      End movement: 4/26/03  
 Institution: Monsanto      Begin release: 4/26/02  
 Recipient: Wheat      End release: 4/26/03  
 Status: Pending      Acre: 9.00  
 Effective date: 5/03/02      CBI status: CBI  
 Phenotype: HT - Glyphosate tolerant

Comments:

Resp person: [REDACTED]  
Parsed name: [REDACTED]Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield, MO 63198

Telephone: [REDACTED] Fax: 636-737-7085

=====

- |  | Initial | Date       |
|--|---------|------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ajd]   | [4/8/02]   |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist               | [JMK]*  | [4/8/02]*  |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex  | [KLo]   | [4/10/02]* |
| 4. <input type="checkbox"/> State response                                     |         |            |

O/d	Loc	Site	Reg			
Interstate	*Dest*MO	*	*SCR	*	[ ]	[ ]
Interstate	*Dest*MT	*	*WR	*	[ ]	[ ]
Interstate	*Orig*MO	*	*SCR	*		
Interstate	*Orig*MT	*	*WR	*		
Release	*	*MT	*	2*WR	*	

- |  |       |            |
|--|-------|------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ajd] | [4/8/02]   |
| 6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw   | [KLo] | [4/29/02]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [KLo] | [4/30/02]  |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |       |            |

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

# CONFIDENTIAL

**Monsanto Reference ID**

2002-562XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-093-07n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-562XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)[@monsanto.com](mailto:monsanto.com)

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

April 26, 2002 - April 26, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:**

HT

**Phenotype:**

Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

**Monsanto Reference ID**

2002-562XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/l2 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/l5 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Monsanto Reference ID**

2002-562XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

10,000 Ship up to 10,000 pounds wheat seed to and from each location.

**ORIGIN:**

MO, MT

**DESTINATION:**

MO, MT

**Ship From:**

MO

\*[(b) (4)] St. Louis County/Province, MO, (b) (4) USA

CONTACT:  
USA (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MO (b) (4)

] - CBI

MT

\*[(b) (4)] Gallatin County/Province, MT, (b) (4) USA

CONTACT:  
USA (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MT, (b) (4)

] - CBI

\*[(b) (4)] Gallatin County/Province, MT, (b) (4) USA

CONTACT:  
USA (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MT, (b) (4)

] - CBI

**Monsanto Reference ID**  
2002-562XRAB

\*[ (b) (4) ] Park County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4) USA,

] - CBI

\*[ (b) (4) ] Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4) USA,

] - CBI

\*[ (b) (4) ] Pondera County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT,

] - CBI

**Ship To:**

MO  
\*[ (b) (4) ] St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4)

] - CBI

**Monsanto Reference ID**

2002-562XRAB

MT

\*[ (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)

] - CBI

[ (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)

] - CBI

[ (b) (4) Park County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)

] - CBI

\*[ (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)

] - CBI

**Monsanto Reference ID**

2002-562XRAB

\*[REDACTED] (b) (4) [REDACTED] Pondera County/Province, MT, (b) (4) USA

[REDACTED] CONTACT: (b) (4), (b) (6), (b) (7)(C) [REDACTED] MT,  
[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

**Monsanto Reference ID**

2002-562XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT (2)

**MT**

[ (b) (4) ] - CBI Gallatin County/Province, MT, USA, 5 acres. [ (b) (4) ]

(b) (4), (b) (6), (b) (7)(C) RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
[ (b) (4), (b) (6), (b) (7)(C) ] - CBI MT [ (b) (4), (b) (6), (b) (7)(C) ] USA [ (b) (4), (b) (6), (b) (7)(C) ]

[ (b) (4) ] - CBI acres. [ (b) (4) ] - CBI Pondera County/Province, MT, USA, 4

(b) (4), (b) (6), (b) (7)(C) RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
[ (b) (4), (b) (6), (b) (7)(C) ] - CBI MT [ (b) (4), (b) (6), (b) (7)(C) ] USA [ (b) (4), (b) (6), (b) (7)(C) ]

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

CONFIDENTIAL

**Monsanto Reference ID**

2002-562XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C. Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C. Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).-

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costle, 622 F.2d 45, 51-52 (D.C. Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F. Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F. Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-562XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-093-07n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-562XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)  
FAX 636/737-7085  
EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

April 26, 2002 - April 26, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

**Monsanto Reference ID**

2002-562XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [  CBI Deleted  ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [  CBI Deleted  ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Monsanto Reference ID**

2002-562XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

10,000 Ship up to 10,000 pounds wheat seed to and from each location.

**ORIGIN:**

MO, MT

**DESTINATION:**

MO, MT

**Ship From:**

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**Monsanto Reference ID**

2002-562XRAB

[ CBI Deleted ] -- \*Park County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Pondera County/Province, MT, USA

**Ship To:**

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Monsanto Reference ID**

2002-562XRAB

**MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Park County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**Monsanto Reference ID**

2002-562XRAB

[ CBI Deleted ] -- \*Pondera County/Province, MT, USA

**Monsanto Reference ID**

2002-562XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT (2)

**MT**

[ CBI Deleted ] -- Gallatin County/Province, MT, USA, 5 acres

[ CBI Deleted ] -- Pondera County/Province, MT, USA, 4 acres

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

**Monsanto Reference ID**

2002-562XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

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4700 River Rd.

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02-093-07n

**1. USDA Reference Number**

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(b) (6), (b) (7)(C)

Phone

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FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

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700 Chesterfield Parkway North

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63198

**4. Duration of Introduction**

Interstate Movement and Release

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**5. Recipient**

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**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

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**designation of transformed line:**

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**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [REDACTED]

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

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Promoter: CMP3/I5 -- [REDACTED]

(b) (4)

CBI

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**8. Introduction** Interstate Movement and Release

10,000 Ship up to 10,000 pounds wheat seed to and from each location.

**ORIGIN:**

MO, MT

**DESTINATION:**

MO, MT

**Ship From:**

MO

\*[ (b) (4) ] St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MO, (b) (4)

] - CBI

MT

\*[ (b) (4) ] Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MT, (b) (4)

] - CBI

\*[ (b) (4) ] Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MT, (b) (4)

] - CBI

**Monsanto Reference ID**  
2002-562XRAB

\*[ (b) (4) Park County/Province, MT (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MT, (b) (4) USA,

] - CBI

\*[ (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MT, (b) (4) USA,

] - CBI

\*[ (b) (4) Pondera County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MT,

] - CBI

**Ship To:**

MO

\*[ (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MO, (b) (4)

] - CBI

**Monsanto Reference ID**

2002-562XRAB

MT

\*[ (b) (4) Gallatin County/Province, MT, (b) (4) USA ] - CBI

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MT [REDACTED]

] - CBI

\*[ (b) (4) Gallatin County/Province, MT, (b) (4) USA ] - CBI

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MT [REDACTED]

] - CBI

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] - CBI

\*[ (b) (4) Gallatin County/Province, MT, (b) (4) USA ] - CBI

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MT, [REDACTED] USA, [REDACTED]

] - CBI

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(b) (4)

Pondera County/Province, MT (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT,  
[REDACTED] USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

**Monsanto Reference ID**

2002-562XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT (2)

**MT**

(b) (4)

Gallatin County/Province, MT, USA, 5 acres.

(b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA

(b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4)

(b) (4)

Pondera County/Province, MT, USA, 4

acres. (b) (4) RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA

] - CBI

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Monsanto Company

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\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

#### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, AgrEvo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

#### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-562XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-093-07n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-562XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)  
FAX 636/737-7085  
EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis MO 63198

**4. Duration of Introduction**

Interstate Movement and Release April 26, 2002 - April 26, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

**Monsanto Reference ID**

2002-562XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal ~~5-enolpyruvylshikimate-3-phosphate synthase~~ gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal ~~5-enolpyruvylshikimate-3-phosphate synthase~~ gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Monsanto Reference ID**

2002-562XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

10,000 Ship up to 10,000 pounds wheat seed to and from each location.

**ORIGIN:**

MO, MT

**DESTINATION:**

MO, MT

**Ship From:**

MO

[  CBI Deleted ] -- \*St. Louis County/Province, MO, USA

MT

[  CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[  CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**Monsanto Reference ID**

2002-562XRAB

[  CBI Deleted ] -- \*Park County/Province, MT, USA

[  CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[  CBI Deleted ] -- \*Pondera County/Province, MT, USA

**Ship To:**

**MO**

[  CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Monsanto Reference ID**

2002-562XRAB

**MT**

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

[ CBI Deleted ] -- \*Park County/Province, MT, USA

[ CBI Deleted ] -- \*Gallatin County/Province, MT, USA

**Monsanto Reference ID**  
2002-562XRAB

[ CBI Deleted ] -- \*Pondera County/Province, MT, USA

**Monsanto Reference ID**

2002-562XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT (2)

**MT**

[ CBI Deleted ] -- Gallatin County/Province, MT, USA, 5 acres

[ CBI Deleted ] -- Pondera County/Province, MT, USA, 4 acres

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-562XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

April 8, 2002

Dear Mr. Brown:

Enclosed is notification 02-093-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-093-07n	Applicant #:	2002-562XRAB
Received:	April 3, 2002	Effective:	May 3, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

[S]

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009668

file copy

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

April 8, 2002

Dear Mr. Ames:

Enclosed is notification 02-093-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-093-07n	Applicant #:	2002-562XRAB
Received:	April 3, 2002	Effective:	May 3, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009669



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

April 8, 2002

Dear Mr. Brown:

Enclosed is notification 02-093-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-093-07n	Applicant #:	2002-562XRAB
Received:	April 3, 2002	Effective:	May 3, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Michael F. Brown

Signature:

(b) (6), (b) (7)(C)

Date: 4/18/02

State: MO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

APR 24 2002

OR120018\_BR\_009670



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Gregory H. Ames, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

April 8, 2002

Dear Mr. Ames:

Enclosed is notification 02-093-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-093-07n	Applicant #:	2002-562XRAB
Received:	April 3, 2002	Effective:	May 3, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: MO MT			
Release destination: MT			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: STEVEN F. BARIL

Signature: (b) (6), (b) (7)(C)

Date: 04-15-02

State: Montana

Rptloc01/R4

APR 15 2002



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An Equal Opportunity Employer

OR120018\_BR\_009671

April 29, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway N.  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after May 3, 2002.

**Interstate movement and Release**  
Notification no. 02-093-07n (2002-562XRAB)  
Regulated article - Wheat  
Destinations - Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
G. Ames, Montana Dept. of Agric., Helena, MT  
File number 02-093-07n

\*\*\*\*\*  
\*\*\* TX REPORT \*\*\*  
\*\*\*\*\*

TRANSMISSION OK

TX/RX NO	0586
CONNECTION TEL	916367377085
SUBADDRESS	
CONNECTION ID	MONSANTO REG AFF
ST. TIME	04/29 12:02
USAGE T	00'24
PGS. SENT	1
RESULT	OK



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Permits &  
Risk  
Assessments

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

April 29, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway N.  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after May 3, 2002.

Interstate movement and Release  
Notification no. 02-093-07n (2002-562XRAB)  
Regulated article - Wheat  
Destinations - Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

MONSANTO



**CONFIDENTIAL**

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

October 13, 2003

Mr. Juan A. Roman  
USDA, APHIS, PPQ  
4700 River Road, Unit 147  
Riverdale, MD, 20737

Re: Farm/Company Address Change, Movement/Release USDA# 02-093-07n (Monsanto# 2002-562XRAB)

Dear Mr. Roman;

(b) (4)

If you have any questions concerning this change, please contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

Cc: R. Stoaks, USDA, APHIS, PPQ, Fort Collins, CO

MONSANTO



## CBI-DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

October 13, 2003

Mr. Juan A. Roman  
USDA, APHIS, PPQ  
4700 River Road, Unit 147  
Riverdale, MD, 20737

Re: Farm/Company Address Change, Movement/Release USDA# 02-093-07n (Monsanto# 2002-562XRAB)

Dear Mr. Roman;

I am writing to inform you that the following movement and release Farm/Company address has changed on approved notification USDA# 02-093-07n (Monsanto# 2002-562XRAB). The site responsible researcher, [CBI DELETED] - CBI, and the Farm/Company name, [CBI DELETED] - CBI, remain the same.

The old address is:

[CBI DELETED] - CBI

The new address is:

[CBI DELETED] - CBI

If you have any questions concerning this change, please contact me at [REDACTED] (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

Cc: R. Stoaks, USDA, APHIS, PPQ, Fort Collins, CO

OR120018\_BR\_009675

*CONFIDENTIAL*

**2002 Wheat Field Test Report  
USDA #02-093-07n                    Monsanto #2002-562XRAB**

**November 6, 2003**

**Biotech Field Compliance Team  
Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
2147316016	Gallatin	MT
2147316014	Pondera	MT

**Gallatin County/MT (2147316016)**

(b) (4)

11/7/03  
OR120018

(b) (4)

Pondera County/MT (2147316014)

(b) (4)

(b) (4)

## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

**CBI-DELETED**

**2002 Wheat Field Test Report  
USDA #02-093-07n                    Monsanto #2002-562XRAB**

**November 6, 2003**

**Biotech Field Compliance Team  
Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
2147316016	Gallatin	MT
2147316014	Pondera	MT

**Gallatin County/MT (2147316016)**

**Planting Date:** 05/13/2002

**Harvest Date:** 09/03/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

**Pondera County/MT (2147316014)**

**Planting Date:** 05/14/2002

**Harvest Date:** 09/10/2002

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

8/14/02 12:27 pm

## Notification Tracking Sheet

=====
 Bp number: 02-220-18n  
 =====

App number: 2002-728XRAB      Begin movement: 9/01/02  
 Received: 8/08/02      End movement: 9/01/03  
 Institution: Monsanto      Begin release: 9/01/02  
 Recipient: Wheat      End release: 9/01/03  
 Status: Pending      Acre: 5.00  
 Effective date: 9/07/02      CBI status: CBI  
 Phenotype: HT - Glyphosate tolerant

Comments:

Resp person: [REDACTED]  
Parsed name: [REDACTED]

(b) (6), (b) (7)(C)

Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield, MO 63198

Telephone: (b) (6), (b) (7)(C)

Fax: 636-737-7085

=====

Initial Date

- |  |           |                |
|--|-----------|----------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ apd ]   | [ 8/15/02 ]    |
| 2. <input type="checkbox"/> Review by biotechnologist                          | [ KLD ] * | [ 08/16/02 ] * |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex  | [ KLD ]   | [ 8/19/02 ] *  |
| 4. <input type="checkbox"/> State response                                     |           |                |

O/d	Loc	Site	Reg			
Interstate	*Dest*HI	*	*WR	*	[ ]	[ ]
Interstate	*Dest*IA	*	*SCR	*	[ ]	[ ]
Interstate	*Dest*KS	*	*SCR	*	[ ]	[ ]
Interstate	*Dest*MO	*	*SCR	*	[ ]	[ ]
Interstate	*Orig*HI	*	*WR	*		
Interstate	*Orig*IA	*	*SCR	*		
Interstate	*Orig*KS	*	*SCR	*		
Interstate	*Orig*MO	*	*SCR	*		
Release	*	*HI	*	1*WR	*	

- |  |         |               |
|--|---------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database   | [ apd ] | [ 8/16/02 ]   |
| 6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw   | [ KLD ] | [ 9/13/02 ] * |
| 7. <input checked="" type="checkbox"/> Enter final data into database  | [ KLD ] | [ 9/13/02 ]   |
| 8. <input type="checkbox"/> If deny, reason: Address incomplete, Signature mismatch,<br>Ph category, Phenotype, Gene, Donor, Marker,<br>Does not qualify |         |               |

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-728XRAB

Permit Unit

August 02, 2002

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-220-18n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-728XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

September 01, 2002 - September 01, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:**

HT

**Phenotype:**

Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-728XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

# **CONFIDENTIAL**

**Monsanto Reference ID**

2002-728XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

2000 Ship up to \_2,000\_\_\_pounds wheat seed to and from each location.

**ORIGIN:**

HI, IA, KS, MO

**DESTINATION:**

HI, IA, KS, MO

**Ship From:****HI**\* [REDACTED] (b) (4) [REDACTED] Honolulu  
County/Province, HI, (b) (4) USACONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED]  
(b) (4), (b) (6), (b) (7)(C) HI [REDACTED] U.S.A. [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

**IA**

\* [REDACTED] (b) (4) [REDACTED] Story County/Province, IA, (b) (4) U.S.A

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] IA, [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A,

] - CBI

**KS**

\* [REDACTED] (b) (4) [REDACTED] Sedgwick County/Province, KS, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] KS, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

# ***CONFIDENTIAL***

**Monsanto Reference ID**

2002-728XRAB

**MO**

\* [REDACTED] (b) (4) [REDACTED] St. Louis County/Province, MO (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] MO, [REDACTED]  
USA [REDACTED]

] - CBI

**Ship To:**

**HI**  
\* [REDACTED] (b) (4) [REDACTED] Honolulu  
County/Province, HI, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED]  
[REDACTED] HI, [REDACTED] U.S.A., [REDACTED] U.S.A., [REDACTED]

] - CBI

**IA**  
[REDACTED] (b) (4) [REDACTED] Story County/Province, IA (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] IA, [REDACTED] U.S.A,  
[REDACTED]

] - CBI

**KS**  
\* [REDACTED] (b) (4) [REDACTED] Sedgwick County/Province, KS, (b) (4) USA

# ***CONFIDENTIAL***

**Monsanto Reference ID**

2002-728XRAB

CONTACT  
[REDACTED]  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

[REDACTED] KS, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

**MO**

[REDACTED]  
(b) (4)

St. Louis County/Province, MO, [REDACTED] (b) (4) USA

CONTACT  
USA [REDACTED]  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

[REDACTED] (b) (4), (b) (6), (b) (7)(C) MO, [REDACTED]

] - CBI

***CONFIDENTIAL***

**Monsanto Reference ID**

2002-728XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

HI (1)

HI

[REDACTED] (b) (4) [REDACTED] Honolulu  
County/Province, HI, USA, 5 acres. (b) (4) [REDACTED]

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) [REDACTED]  
(b) (4), (b) (6), (b) (7)(C) HI (b) (4), (b) (6), (b) (7)(C) U.S.A. [REDACTED]

] - CBI

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-728XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)  
[Redacted]

Monsanto Company

August 02, 2002

## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982)..

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

#### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO



MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

## CB1-DELTA TD

**Monsanto Reference ID**

2002-728XRAB

Permit Unit

August 02, 2002

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-220-18n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-728XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)  
[REDACTED]

Phone (b) (6), (b) (7)(C)  
FAX 636/737-7085  
EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis MO 63198

**4. Duration of Introduction**

Interstate Movement and Release

September 01, 2002 - September 01, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

# **CBI-DELETED**

**Monsanto Reference ID**

2002-728XRAB

**designation of transformed line:** 33391**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

# **CBI-DELETED**

**Monsanto Reference ID**

2002-728XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

2000 Ship up to \_2,000\_\_\_ pounds wheat seed to and from each location.

**ORIGIN:**

HI, IA, KS, MO

**DESTINATION:**

HI, IA, KS, MO

**Ship From:****HI**

[ CBI Deleted ] -- \*Honolulu County/Province, HI, USA

**IA**

[ CBI Deleted ] -- \*Story County/Province, IA, U.S.A

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

# **CBI-DELETED**

**Monsanto Reference ID**

2002-728XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Ship To:****HI**

[ CBI Deleted ] -- \*Honolulu County/Province, HI, USA

**IA**

[ CBI Deleted ] -- \*Story County/Province, IA, U.S.A

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**CBI-DELETED**

**Monsanto Reference ID**  
2002-728XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

# **CBI-DELETED**

**Monsanto Reference ID**  
2002-728XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

HI (1)

**HI**

[ CBI Deleted ] -- Honolulu County/Province, HI, USA, 5 acres

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

*CBI-DELETED*

Monsanto Reference ID

2002-728XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of my knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)  
[Redacted area]

Monsanto Company

August 02, 2002

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**CBI-DELETED**

**Monsanto Reference ID**

2002-728XRAB

Permit Unit

August 02, 2002

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-220-18n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-728XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

**4. Duration of Introduction**

Interstate Movement and Release

September 01, 2002 - September 01, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:**

HT

**Phenotype:**

Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

# **CBI-DELETED**

**Monsanto Reference ID**

2002-728XRAB

**designation of transformed line:** 33391**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**GENE OF INTEREST**

Promoter: CMP3/I5 -- [ CBI Deleted ]

**CBI**

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# **CBI-DELETED**

**Monsanto Reference ID**

2002-728XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release2000 Ship up to 2,000 pounds wheat seed to and from each location.**ORIGIN:**

HI, IA, KS, MO

**DESTINATION:**

HI, IA, KS, MO

**Ship From:****HI**[  CBI Deleted ] -- \*Honolulu County/Province, HI, USA**IA**[  CBI Deleted ] -- \*Story County/Province, IA, U.S.A**KS**[  CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

# **CBI-DELETED**

**Monsanto Reference ID**

2002-728XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**Ship To:****HI**

[ CBI Deleted ] -- \*Honolulu County/Province, HI, USA

**IA**

[ CBI Deleted ] -- \*Story County/Province, IA, U.S.A

**KS**

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**CBI-DELETED**

**Monsanto Reference ID**  
2002-728XRAB

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**CBI-DELETED**

**Monsanto Reference ID**

2002-728XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

HI (1)

**HI**

[ CBI Deleted ] -- Honolulu County/Province, HI, USA, 5 acres

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**CBI-DELETED**

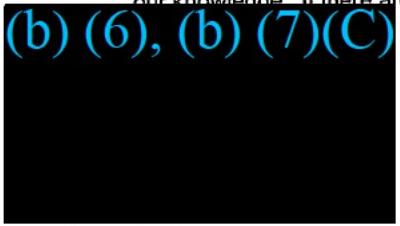
**Monsanto Reference ID**

2002-728XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

A large black rectangular redaction box covers the area where a signature would typically be placed.

Monsanto Company

August 02, 2002

file copy

Dr. Neil Reimer, Manager  
Plant Quarantine Branch  
Hawaii Department of Agriculture  
701 Ilalo Street  
Honolulu, HI 96813

August 14, 2002

Dear Dr. Reimer:

Enclosed is notification 02-220-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-220-18n                      Applicant #: 2002-728XRAB  
Received: August 8, 2002                      Effective: September 7, 2002  
Institution: Monsanto                          Recipient: Wheat  
Interstate destination: HI IA KS MO  
Release destination: HI

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009708

file copy

Mr. Charles Stoltenow  
IA Department of Agriculture and Land Stewardship  
First Floor, Wallace building  
East 9th Street and Grand Avenue  
Des Moines, IA 50319

August 14, 2002

Dear Mr. Stoltenow:

Enclosed is notification 02-220-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-220-18n                      Applicant #: 2002-728XRAB  
Received: August 8, 2002                      Effective: September 7, 2002  
Institution: Monsanto                          Recipient: Wheat  
Interstate destination: HI IA KS MO  
Release destination: HI

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009709

file copy

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

August 14, 2002

Dear Mr. Sim IV:

Enclosed is notification 02-220-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-220-18n                      Applicant #: 2002-728XRAB  
Received: August 8, 2002                      Effective: September 7, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: HI IA KS MO  
Release destination: HI

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009710

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

August 14, 2002

Dear Mr. Brown:

Enclosed is notification 02-220-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-220-18n                      Applicant #: 2002-728XRAB  
Received: August 8, 2002                      Effective: September 7, 2002  
Institution: Monsanto                        Recipient: Wheat  
Interstate destination: HI IA KS MO  
Release destination: HI

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009711



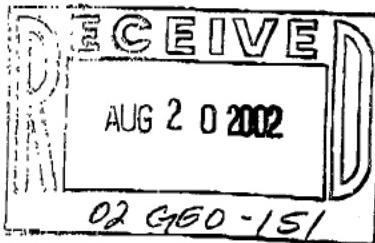
United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Dr. Neil Reimer, Manager  
Plant Quarantine Branch  
Hawaii Department of Agriculture  
701 Ilalo Street  
Honolulu, HI 96813



August 14, 2002

Dear Dr. Reimer:

Enclosed is notification 02-220-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-220-18n                      Applicant #: 2002-728XRAB  
 Received: August 8, 2002                      Effective: September 7, 2002  
 Institution: Monsanto                            Recipient: Wheat  
 Interstate destination: HI IA KS MO  
 Release destination: HI

Should you have comments, please respond either by telephone (301) 734-5767 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept of Agriculture, 1849 Auiki St., Honolulu, HI 96819.  
 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 9 Sept 2002

State: Hawaii Rptloc01/R4

\*The movement of wheat seed into Hawaii is unrestricted. Wheat plantlets and green tissue require state permits. Please call Carol Okada at (808) 586-0861 for information on this type of movement into Hawaii.

832-0566



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An Equal Opportunity Employer

SEP 9 2002

OR120018\_BR\_009712



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Charles Stoltenow  
IA Department of Agriculture and Land Stewardship  
First Floor, Wallace building  
East 9th Street and Grand Avenue  
Des Moines, IA 50319

August 14, 2002

Dear Mr. Stoltenow:

Enclosed is notification 02-220-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-220-18n	Applicant #:	2002-728XRAB
Received:	August 8, 2002	Effective:	September 7, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: HI IA KS MO			
Release destination: HI			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

#### STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: C. R. Stoltenow

Signature: (b) (6), (b) (7)(C)

Date: September 11, 2002

State: Iowa

Rptloc01/R4



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SEP 11 2002

OR120018\_BR\_009713

TOTAL P.12



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

August 14, 2002

Dear Mr. Sim IV:

Enclosed is notification 02-220-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-220-18n                      Applicant #: 2002-728XRAB  
Received: August 8, 2002                      Effective: September 7, 2002  
Institution: Monsanto                          Recipient: Wheat  
Interstate destination: HI IA KS MO  
Release destination: HI

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



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OR120018\_BR\_009714



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

August 14, 2002

Dear Mr. Brown:

Enclosed is notification 02-220-18n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-220-18n	Applicant #:	2002-728XRAB
Received:	August 8, 2002	Effective:	September 7, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: HI IA KS MO			
Release destination: HI			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 08/21/02

State: MO

Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_009715

September 13, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C),

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after September 13, 2002.

**Interstate movement and Release**  
**Notification no. 02-220-18n (2002-728XRAB)**  
**Regulated article - Wheat**  
**Destinations - Hawaii, Iowa, Kansas, Missouri**

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The movement of wheat seed into Hawaii is unrestricted. Wheat plantlets and green tissue require state permits. Please call Ms. Carol Okada at (808) 832-0566 for information on this type of movement into Hawaii.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 1849 Auiki Street, Honolulu, Hawaii 96819, at each of the following times:
  - a) All planting, pollinating and harvesting dates of each field trial.
  - b) Any changes to the field sites, recommended conditions, or other related matters.
  - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
  - a) The germination of volunteer wheat after harvest.

- b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

The report should be submitted to the Plant Quarantine Branch, 1849 Auiki Street, Honolulu, Hawaii, 96819, with a copy to Ms. Carol Okada, within six months of completion or termination of the test.

4. The introduction of any organism other than corn seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Dr. Neil Reimer, Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

cc:

N. Reimer, Hawaii Dept. of Agric., Honolulu, HI  
C. Stoltenow, Iowa Dept. of Agric. and Land Stewardship, Des Moines, IA  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
File number 02-220-18n

*CONFIDENTIAL*

**2002 Wheat Field Test Report  
USDA #02-220-18n                    Monsanto #2002-728XRAB**

**January 7, 2004**

**Biotech Field Compliance Team  
Monsanto Company**

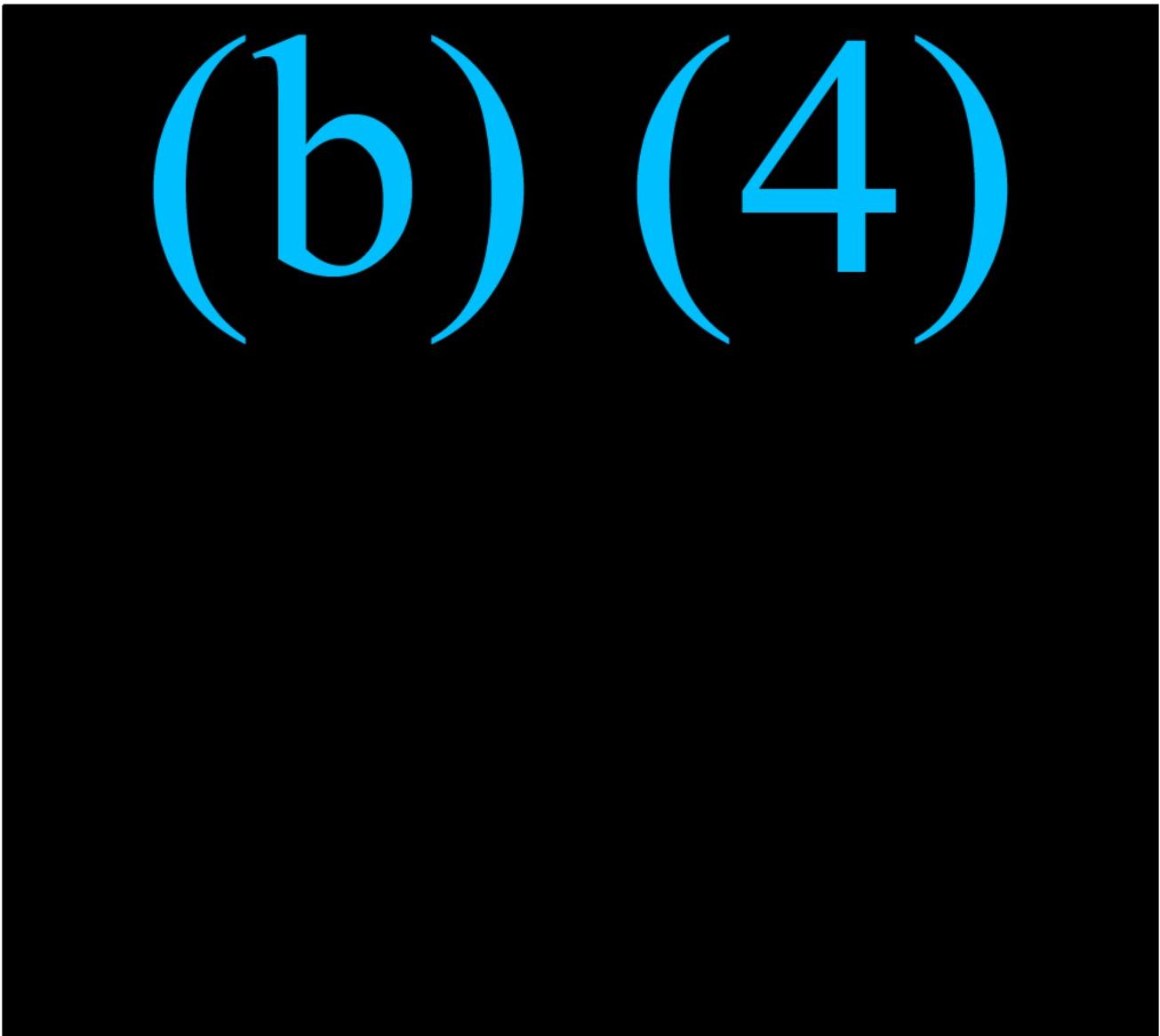
**Location**  
2147316661

**County**  
Honolulu

**State**  
HI

**Honolulu County/HI (2147316661)**

(b) (4)



*end  
1/8/04*

(b) (4)

## **CONFIDENTIAL BUSINESS JUSTIFICATION**

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

*CBI-DELETED*

**2002 Wheat Field Test Report  
USDA #02-220-18n                    Monsanto #2002-728XRAB**

**January 7, 2004**

**Biotech Field Compliance Team  
Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
2147316661	Honolulu	HI

**Honolulu County/HI (2147316661)**

**Planting Date:** 12/10/2002

**Harvest Date:** 04/21/2003

**Destruct Date:** 05/19/2003

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

8/27/02 7:35 am

Notification Tracking Sheet

=====  
Bp number: 02-231-13n  
=====

App number: 2002-738XRAB      Begin movement: 9/13/02  
Received: 8/19/02      End movement: 9/13/03  
Institution: Monsanto      Begin release: 9/13/02  
Recipient: Wheat      End release: 9/13/03  
Status: Pending      Acre: 20.00  
Effective date: 9/18/02      CBI status: CBI  
Phenotype: HT - Glyphosate tolerant  
Comments:  
Resp person: [REDACTED] (b) (6), (b) (7)(C)  
Parsed name: [REDACTED]

Address1: Monsanto Company  
Address2: 700 Chesterfield Parkway N.

Address3:

Address4:

City/State/Zip: Chesterfield, MO 63198

Telephone: [REDACTED] (b) (6), (b) (7)(C)      Fax: [REDACTED] 636-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[ajd]	[8/27/02]
2. <input checked="" type="checkbox"/> Review by biotechnologist OR120018_BR_009723	[JMC]*	[8/27/02]*
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[KLP]	[8/30/02]*

## 4. [ ] State response

	O/d	Loc	Site	Reg	[ ]	[ ]	[ ]
Interstate	*Dest*CO	*	*WR	*	[ ]	[ ]	[ ]
Interstate	*Dest*KS	*	*SCR	*	[ ]	[ ]	[ ]
Interstate	*Dest*MO	*	*SCR	*	[ ]	[ ]	[ ]
Interstate	*Dest*NE	*	*SCR	*	[ ]	[ ]	[ ]
Interstate	*Orig*CO	*	*WR	*	[ ]	[ ]	[ ]
Interstate	*Orig*KS	*	*SCR	*	[ ]	[ ]	[ ]
Interstate	*Orig*MO	*	*SCR	*	[ ]	[ ]	[ ]
Interstate	*Orig*NE	*	*SCR	*	[ ]	[ ]	[ ]
Release	*	*KS	*	1*SCR	*	[ ]	[ ]
Release	*	*NE	*	1*SCR	*	[ ]	[ ]

5.  Enter genes into database [ apd ] [ 8/27/02 ]
6.  Letter of acknowledgement/denial/withdraw [ KLD ] [ 9/4/02 ]\*
7.  Enter final data into database [ KLD ] [ 9/6/02 ]
8. [ ] If deny, reason: Address incomplete, Signature mismatch,  
Ph category, Phenotype, Gene, Donor, Marker,  
Does not qualify

OR120018\_BR\_009724

MONSANTO



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

**Monsanto Reference ID**

2002-738XRAB

Permit Unit

August 14, 2002

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-231-13n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-738XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North  
St. Louis MO  
63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

OR120018\_BR\_009725  
63198

**4. Duration of Introduction**

**4. Duration of Introduction:**

Interstate Movement and Release

September 13, 2002 - September 13, 2003

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from hybrid/cultivar Bobwhite

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-738XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/l2 -- [REDACTED]

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

OR120018 BR 009727

Promoter: CMP3/I5 -- [REDACTED]

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

# **CONFIDENTIAL**

**Monsanto Reference ID**

2002-738XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens**8. Introduction** Interstate Movement and Release

2000 pounds of wheat may be shipped for the term of this notification Ship up to 1000 pounds wheat seed to and from each location.

**ORIGIN:**

CO, KS, MO, NE

**DESTINATION:**

CO, KS, MO, NE

**Ship From:**

CO

\* USA

(b) (4)

Yuma County/Province, CO, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) CO, (b) (4) USA,

] - CBI

\*[ (b) (4) Arapaho County/Province, CO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

KS

\*[ (b) (4) County/Province, KS, (b) (4) (b) (4) Ellis

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C)

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-738XRAB

\* [REDACTED] (b) (4) [REDACTED] Sedgwick County/Province, KS, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] KS, [REDACTED] (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

\* [REDACTED] (b) (4) [REDACTED] Thomas County/Province, KS, (b) (4)  
USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED]  
(b) (4), (b) (6), (b) (7)(C) KS, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

OR120018\_BR\_009731

**MO**

\*[REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] MO, [REDACTED]  
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

**NE**

\*[REDACTED] (b) (4) Lincoln County/Province, NE, (b) (4)  
U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] NE,  
(b) (4), (b) (6), (b) (7)(C) U.S.A., [REDACTED]

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-738XRAB

**Ship To:**

CO

\*[REDACTED] (b) (4) Yuma County/Province, CO, (b) (4)  
USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) CO, [REDACTED] USA,

] - CBI

\*[REDACTED] (b) (4) Arapaho County/Province, CO, (b) (4) USA

OR120018\_BR\_009733

CONTACT: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) CO, [REDACTED] USA,

] - CBI

KS

\*[ (b) (4) ] Ellis  
County/Province, KS (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C)

] - CBI

\*[ (b) (4) ] Sedgwick County/Province, KS (b) (4) USA

***CONFIDENTIAL***

**Monsanto Reference ID**

2002-738XRAB

CONTACT:  
(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

KS, (b) (4), (b) (6), (b) (7)(C) USA,

] - CBI

\*  
USA

(b) (4)

Thomas County/Province, KS, (b) (4)

CONTACT:  
(b) (4), (b) (6), (b) (7)(C)

KS, (b) (4), (b) (6), (b) (7)(C)

] - CBI

OR120018\_BR\_009735

MO

\*

(b) (4)

St. Louis County/Province, MO, (b) (4) USA

CONTACT:  
USA [REDACTED]

(b) (4), (b) (6), (b) (7)(C)

MO, [REDACTED]  
(b) (4), (b) (5), (b) (7)(E)

] - CBI

NE

\*[  
U.S.A.

(b) (4)

Lincoln County/Province, NE, [REDACTED] (b) (4)

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) [REDACTED] NE,  
(b) (4), (b) (6), (b) (7)(C) U.S.A., [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

**CONFIDENTIAL**

**Monsanto Reference ID**

2002-738XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

KS (1), NE (1)

**KS**

[REDACTED] (b) (4) Thomas County/Province, KS, USA, 10  
acres. [REDACTED] (b) (4)

**RESPONSIBLE PERSON/RESEARCHER:** [REDACTED]  
(b) (4), (b) (6), (b) (7)(C)

[REDACTED] (b) (4), (b) (6), (b) (7)(C)  
[REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

**NE**

**OR120018\_BR\_009737**

[REDACTED] (b) (4)

[REDACTED] Lincoln County/Province, NE, U.S.A., 10 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) NE, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO



*CONFIDENTIAL*

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

<http://www.monsanto.com>

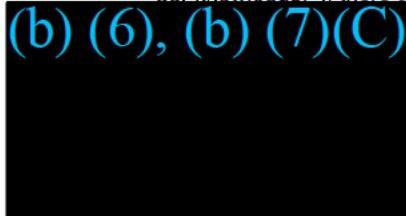
**Monsanto Reference ID**

2002-738XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

A large black rectangular redaction box covers the area where a signature would typically be placed.

Monsanto Company

August 14, 2002

OR120018\_BR\_009739

OR120018\_BR\_009740

## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).-

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is

exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

OR120018\_BR\_009742

Monsanto ID: 2002-738XRAB

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information in the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

**OR20018-BR 009743**

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Monsanto ID: 2002-738XRAB

### **Names And Information About Genes, Promoters, Terminators And Expressed Traits**

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organsim appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage

OR120018.BP1.009745

of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

OR120018\_BR\_009746

MONSANTO



CBH DEL ETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-738XRAB

Permit Unit

August 14, 2002

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

02-231-13n

**1. USDA Reference Number**

**2. Applicant Reference Number** 2002-738XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North  
St. Louis MO  
63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

QR120018\_BR\_009747

**4. Duration of Introduction**

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from hybrid/cultivar Bobwhite

# **CBI-DELETED**

**Monsanto Reference ID**

2002-738XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST****OR120018\_BR\_009749**

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**CBI-DELETED**

**Monsanto Reference ID**

2002-738XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

2000 pounds of wheat may be shipped for the term of this notification Ship up to 1000 pounds wheat seed to and from each location.

**ORIGIN:**

CO, KS, MO, NE

**DESTINATION:**

CO, KS, MO, NE

**Ship From:**

CO

[ CBI Deleted ] -- \*Yuma County/Province, CO, USA

OR120018\_BR\_009751

[ CBI Deleted ] -- \*Arapaho County/Province, CO, USA

**KS**

[ CBI Deleted ] -- \*Ellis County/Province, KS

**CBI-DELETED**

**Monsanto Reference ID**

2002-738XRAB

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

[ CBI Deleted ] -- \*Thomas County/Province, KS, USA

OR120018\_BR\_009753

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**NE**

[ CBI Deleted ] -- \*Lincoln County/Province, NE, U.S.A.

**CBI-DELETED**

**Monsanto Reference ID**

2002-738XRAB

**Ship To:**

**CO**

[  CBI Deleted ] -- \*Yuma County/Province, CO, USA

[  CBI Deleted ] -- \*Arapaho County/Province, CO, USA

**OR120018\_BR\_009755**

**KS**

[ CBI Deleted ] -- \*Ellis County/Province, KS

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**CBI-DELETED**

**Monsanto Reference ID**

2002-738XRAB

[ CBI Deleted ] -- \*Thomas County/Province, KS, USA

OR120018\_BR\_009757

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**NE**

[ CBI Deleted ] -- \*Lincoln County/Province, NE, U.S.A.

**CBI-DELETED**

**Monsanto Reference ID**

2002-738XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

KS (1), NE (1)

**KS**

[  CBI Deleted ] -- Thomas County/Province, KS, USA, 10 acres

**NE**

[  CBI Deleted ] -- Lincoln County/Province, NE, U.S.A., 10 acres

OR120018\_BR\_009759

OR120018\_BR\_009760

MONSANTO



CB1-D-EFL-180

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

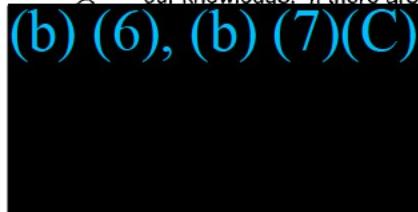
**Monsanto Reference ID**

2002-738XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 14, 2002

OR120018\_BR\_009761

OR120018\_BR\_009762

MONSANTO



RECORDED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

**Monsanto Reference ID**

2002-738XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

August 14, 2002

02-231-13n

- 1. USDA Reference Number**
- 2. Applicant Reference Number** 2002-738XRAB
- 3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North  
St. Louis MO  
63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)

@monsanto.com

OR120018\_BR\_009763

- 4. Duration of Introduction**

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate tolerant

Cultivar(s)/Variety(ies): Lines derived from hybrid/cultivar Bobwhite

*CP4-EPSPS*

**Monsanto Reference ID**

2002-738XRAB

**designation of transformed line:**

33391

**Constructs:** PV-TXGT10

**GENE OF INTEREST**

Promoter: CMoVa/I2 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**GENE OF INTEREST**

OR120018\_BR\_009765

Promoter: CMP3/I5 -- [ CBI Deleted ]

*CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* ~~EPSPS~~<sup>EPSPS</sup> gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Monsanto Reference ID**

2002-738XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

2000 pounds of wheat may be shipped for the term of this notification. Ship up to 1000 pounds wheat seed to and from each location.

**ORIGIN:**

CO, KS, MO, NE

**DESTINATION:**

CO, KS, MO, NE

**Ship From:**

CO

[ CBI Deleted ] -- \*Yuma County/Province, CO, USA

OR120018\_BR\_009767

[ CBI Deleted ] -- \*Arapaho County/Province, CO, USA

**KS**

[ CBI Deleted ] -- \*Ellis County/Province, KS

**Monsanto Reference ID**

2002-738XRAB

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

[ CBI Deleted ] -- \*Thomas County/Province, KS, USA

OR120018\_BR\_009769

**MO**

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**NE**

[ CBI Deleted ] -- \*Lincoln County/Province, NE, U.S.A.

**Monsanto Reference ID**

2002-738XRAB

**Ship To:**

**CO**

[  CBI Deleted ] -- \*Yuma County/Province, CO, USA

[  CBI Deleted ] -- \*Arapaho County/Province, CO, USA

OR120018\_BR\_009771

**KS**

[ CBI Deleted ] -- \*Ellis County/Province, KS

[ CBI Deleted ] -- \*Sedgwick County/Province, KS, USA

**Monsanto Reference ID**

2002-738XRAB

[ CBI Deleted ] -- \*Thomas County/Province, KS, USA

MO

OR120018\_BR\_009773

[ CBI Deleted ] -- \*St. Louis County/Province, MO, USA

**NE**

[ CBI Deleted ] -- \*Lincoln County/Province, NE, U.S.A.

**Monsanto Reference ID**

2002-738XRAB

**Release Site:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

KS (1), NE (1)

**KS**

[ CBI Deleted ] -- Thomas County/Province, KS, USA, 10 acres

**NE**

[ CBI Deleted ] -- Lincoln County/Province, NE, U.S.A., 10 acres

OR120018\_BR\_009775

OR120018\_BR\_009776

MONSANTO



MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
<http://www.monsanto.com>

RECORDED - INDEXED

**Monsanto Reference ID**

2002-738XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 14, 2002

OR120018\_BR\_009777

OR120018\_BR\_009778

file copy

Mr. Mitch Yergert  
Colorado Department of Agriculture  
700 Kipling Street - Suite 4000  
Lakewood, CO 80215-5894

August 27, 2002

Dear Mr. Yergert:

Enclosed is notification 02-231-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-231-13n	Applicant #:	2002-738XRAB
Received:	August 19, 2002	Effective:	September 18, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: CO KS MO NE			
Release destination: KS NE			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt. **OR120018\_BR\_009779**

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009780

file copy

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

August 27, 2002

Dear Mr. Sim IV:

Enclosed is notification 02-231-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-231-13n

Applicant #: 2002-738XRAB

Received: August 19, 2002

Effective: September 18, 2002

Institution: Monsanto

Recipient: Wheat

Interstate destination: CO KS MO NE

Release destination: KS NE

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3(c) that APHIS provide an acknowledgement within 30 days of receipt.

OR120018\_BR\_095781

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009782

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

August 27, 2002

Dear Mr. Brown:

Enclosed is notification 02-231-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-231-13n	Applicant #:	2002-738XRAB
Received:	August 19, 2002	Effective:	September 18, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: CO KS MO NE			
Release destination: KS NE			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3(c) that you provide an acknowledgement within 30 days of receipt.

Sincerely,

OR120018\_BR\_000783

sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009784

file copy

Mr. Stephen V. Johnson, State Entomologist  
Bureau of Plant Industry  
Nebraska Department of Agriculture  
301 Centennial Mall South - 4th Floor  
Lincoln, NE 68509-4756

August 27, 2002

Dear Mr. Johnson:

Enclosed is notification 02-231-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-231-13n	Applicant #:	2002-738XRAB
Received:	August 19, 2002	Effective:	September 18, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO KS MO NE		
Release destination:	KS NE		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.13 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

DR120018\_BR\_009785

sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4

OR120018\_BR\_009786



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

RECEIVED  
COLO. DEPT. OF AGRICULTURE  
Biotechnology  
Regulatory  
Services  
2002 AUG 30 PM 1:47

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Mitch Yergert  
Colorado Department of Agriculture **PLANT INDUSTRY DIVISION**  
700 Kipling Street - Suite 4000  
Lakewood, CO 80215-5894

August 27, 2002

Dear Mr. Yergert:

Enclosed is notification 02-231-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-231-13n	Applicant #:	2002-738XRAB
Received:	August 19, 2002	Effective:	September 18, 2002
Institution:	Monsanto	Recipient:	Wheat
Interstate destination: CO KS MO NE			
Release destination: KS NE			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

sincerely,

(b) (6), (b) (7)(C)

OR120018\_BR\_009787

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: MITCHELL YERGERT

Signature:   
(b) (6), (b) (7)(C)

Date: AUGUST 30, 2002

State: COLORADO

Rptloc01/R4



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OR120018\_BR\_009788



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Tom Sim IV, Administrator  
Plant Protection and Weed Control Section  
Kansas State Board of Agriculture  
901 S. Kansas Avenue  
Topeka, KS 66612-1281

August 27, 2002

Dear Mr. Sim IV:

Enclosed is notification 02-231-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-231-13n

Applicant #: 2002-738XRAB

Received: August 19, 2002

Effective: September 18, 2002

Institution: Monsanto

Recipient: Wheat

Interstate destination: CO KS MO NE

Release destination: KS NE

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt. **OR120018\_BR\_009789**

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



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OR120018\_BR\_009790



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

August 27, 2002

Dear Mr. Brown:

Enclosed is notification 02-231-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-231-13n

Applicant #: 2002-738XRAB

Received: August 19, 2002

Effective: September 18, 2002

Institution: Monsanto

Recipient: Wheat

Interstate destination: CO KS MO NE

Release destination: KS NE

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt. **OR120018\_BR\_009791**

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

---

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 9/3/02

State: MO

Rptloc01/R4



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OR120018\_BR\_009792

TOTAL P.09



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

Mr. Stephen V. Johnson, State Entomologist  
Bureau of Plant Industry  
Nebraska Department of Agriculture  
301 Centennial Mall South - 4th Floor  
Lincoln, NE 68509-4756

August 27, 2002

Dear Mr. Johnson:

Enclosed is notification 02-231-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 02-231-13n

Applicant #: 2002-738XRAB

Received: August 19, 2002

Effective: September 18, 2002

Institution: Monsanto

Recipient: Wheat

Interstate destination: CO KS MO NE

Release destination: KS NE

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt. **OR120018\_BR\_009793**

Sincerely,

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessments  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

---

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Rptloc01/R4



APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018\_BR\_009794

September 4, 2002

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Parkway North  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after September 18, 2002.

Interstate movement and Release

Notification no. 02-231-13n (2002-738XRAB)

Regulated article - Wheat

Destinations - Colorado, Kansas, Missouri, Nebraska

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

OR120018 BR-009795

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

CC:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
S. Johnson, Nebraska Dept. of Agric., Lincoln, NE  
File number 02-231-13n

OR120018\_BR\_009796

## Confirmation Report-Memory Send

Time : Sep-04-02 03:35pm  
Tel line 1 :  
Tel line 2 :  
Name :

Job number : 592  
Date : Sep-04 03:33pm  
To : 916367377085  
Document Pages : 02  
Start time : Sep-04 03:33pm  
End time : Sep-04 03:35pm  
Pages sent : 02  
Job number : 592

\*\*\* SEND SUCCESSFUL \*\*\*



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

Biotechnology  
Regulatory  
Services

4700 River Road, Unit 147  
Riverdale, Maryland  
20737-1236

OR120018\_BR\_009797  
September 4, 2002

(b) (6), (b) (7)(C)

Merckle Company  
700 Chesterfield Parkway North  
St. Louis, MO 63121

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after September 18, 2002.

Interstate movement and Release

Notification no. 02-231-13n (2002-738XRA8)

Regulated article - Wheat

Destinations - Colorado, Kansas, Missouri, Nebraska

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist  
Biotechnology Program Operations  
Permits and Risk Assessment  
Plant Protection and Quarantine

Enclosure

cc:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO  
T. Sim, Kansas State Board of Agric., Topeka, KS  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
S. Johnson, Nebraska Dept. of Agric., Lincoln, NE



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OR120018\_BR\_009798

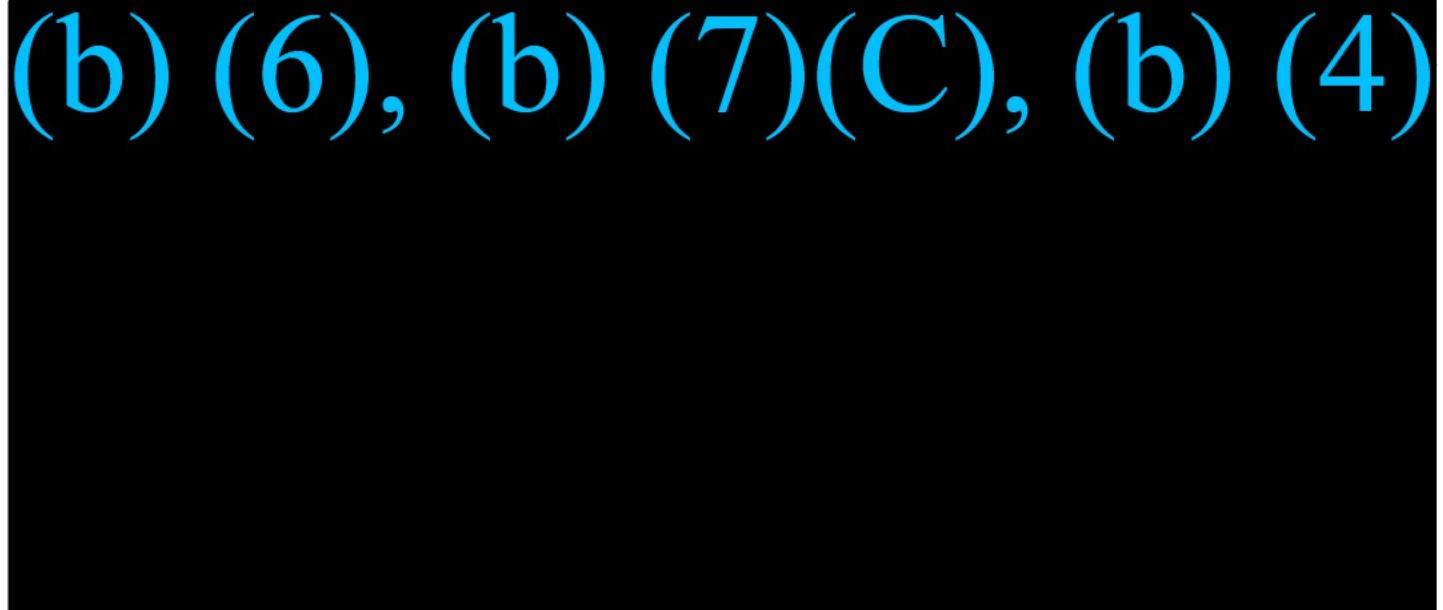
CONTAINS CBI CONFIDENTIAL CONTAINS CBI

3  
C

## NOTIFICATION FIELD SITE INSPECTION WORKSHEET

*When completed, this is an Internal PPQ Document*

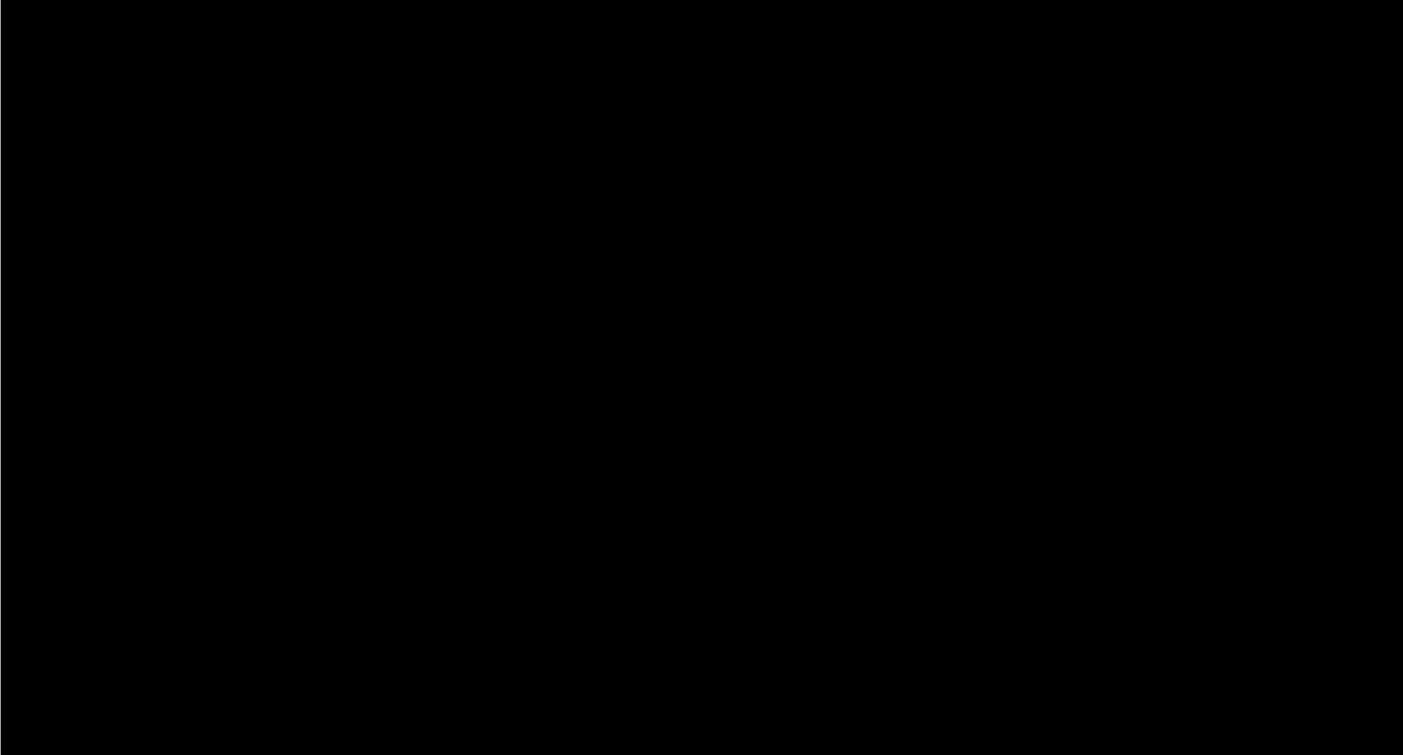
(b) (6), (b) (7)(C), (b) (4)



(b) (6), (b) (7)(C), (b) (4)



(b) (6), (b) (7)(C), (b) (4)



Revised 7/2/03

CONTAINS CBI CONFIDENTIAL CONTAINS CBI  
ORI 20018 BR\_009800

*CONFIDENTIAL*

**2002 Wheat Field Test Report**  
**USDA #02-231-13n**      **Monsanto #2002-738XRAB**

**January 7, 2004**

**Biotech Field Compliance Team**  
**Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
2147316102	Thomas	KS
2147315953	Lincoln	NE

**Thomas County/KS (2147316102)**

(b) (4)

OR120018\_BR\_009801

(b) (4)

(b) (4)

USDA# 02-231-13n

Page 1 of 3

Monsanto #2002-738XRAB

OR120018\_BR\_009802

008  
11/8/04

(b) (4)

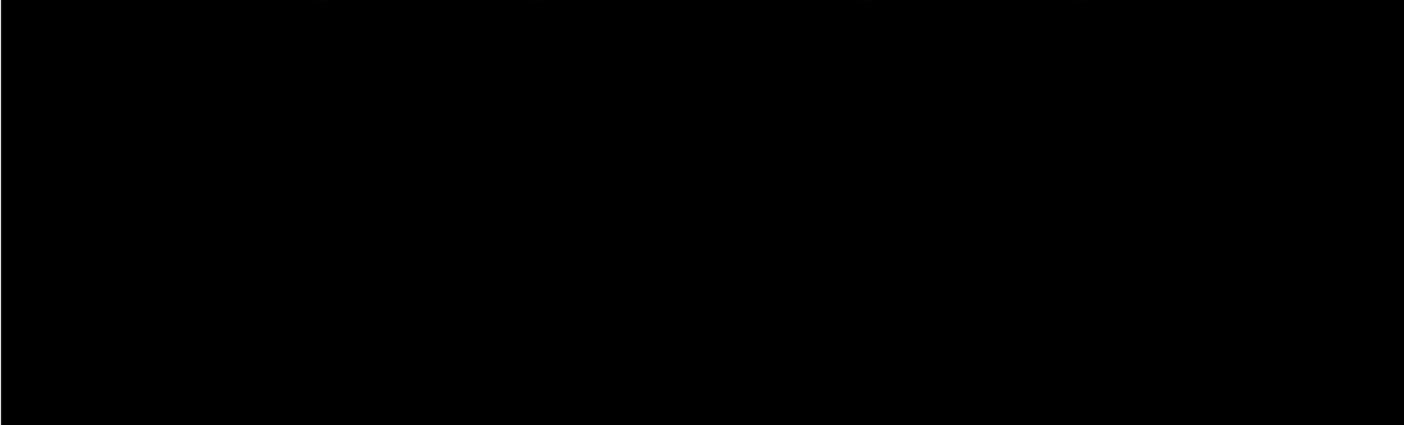
Lincoln County/NE (2147315953)

(b) (4)

OR120018\_BR\_009803

(b) (4)

(b) (4)



USDA# 02-231-13n

Page 2 of 3

Monsanto #2002-738XRAB

OR120018\_BR\_009804

(b) (4)

OR120018\_BR\_009805

USDA# 02-231-13n

Page 3 of 3

Monsanto #2002-738XRAB

**OR120018\_BR\_009806**

## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

**OR120018 BR 009807**

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by

request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below\*.

\* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

### **Field Monitoring Data as CBI**

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

### **Identification of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI ] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

OR120018\_BR\_009809



*CBI-DELETED*

**2002 Wheat Field Test Report**  
**USDA #02-231-13n                    Monsanto #2002-738XRAB**

**January 7, 2004**

**Biotech Field Compliance Team  
Monsanto Company**

<b><u>Location</u></b>	<b><u>County</u></b>	<b><u>State</u></b>
2147316102	Thomas	KS
2147315953	Lincoln	NE

**Thomas County/KS (2147316102)**

**Planting Date:** 09/25/2002

**Harvest Date:** 07/02/2003

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]  
**OR120018\_BR\_009811**

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

**Lincoln County/NE (2147315953)**

**Planting Date:** 10/07/2002

**Destruct Date:** 06/09/2003

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

OR120018\_BR\_009813

USDA# 02-231-13n

Page 2 of 2

Monsanto #2002-738XRAB

**OR120018\_BR\_009814**